

Case No. 21-cv-01093-LPS

**UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

In re

MALLINCKRODT PLC, *et al.*

Debtors.

ATTESTOR LIMITED AND HUMANA INC.,

Appellants,

v.

MALLINCKRODT PLC, *et al.*,

Appellees.

**APPEAL FROM THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

APPENDIX VOL. 7 (A-6950- A-7486) TO APPELLANT’S OPENING BRIEF

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¹ This is an exemplar of the proofs of claim of Humana Inc. subject to this appeal. The remaining proofs of claim of Humana Inc. subject to this appeal are substantially identical to this proof of claim and have been assigned the following claim numbers: 3344, 3420, 4175, 4201, 4196, 4203, 4366, 5099, 4542, 4556, and 4565. These claims have been omitted due to their voluminous nature and can be accessed at: <https://restructuring.primeclerk.com/mallinckrodt/Home-ClaimInfo>.

² This is an exemplar of the proofs of claim of Avon Holdings I LLC as Transferee of United HealthCare Services Inc. subject to this appeal. The remaining proofs of claim of Avon Holdings I LLC as Transferee of United HealthCare Services Inc. subject to this appeal are substantially identical to this proof of claim and have been assigned the following claim numbers: 5171, 5717, 5638, 4335, 4314, 4288, 4211, 4593, 4219, and 4131. These claims have been omitted due to their voluminous nature and can be accessed at: <https://restructuring.primeclerk.com/mallinckrodt/Home-ClaimInfo>.

³ This is an exemplar of the proofs of claim of Avon Holdings I LLC as Transferee of OptumRx Group Holdings, Inc. and OptumRx Holdings, LLC subject to this appeal. The remaining proofs of claim of Avon Holdings I LLC as Transferee of OptumRx Group Holdings, Inc. and OptumRx Holdings, LLC subject to this appeal are substantially identical to this proof of claim and have been assigned the following claim numbers: 5309, 5288, 5010, 5787, 5805, 5825, 5803, 5790, 5908, and 5938. These claims have been omitted due to their voluminous nature and can be accessed at: <https://restructuring.primeclerk.com/mallinckrodt/Home-ClaimInfo>.

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**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

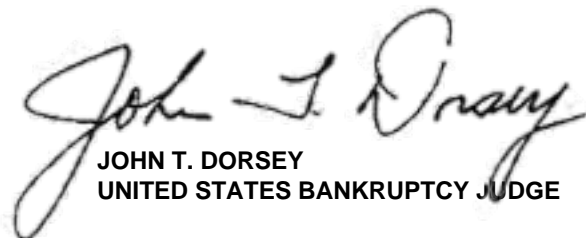
In re:)	Chapter 11
)	
MALLINCKRODT PLC, <i>et al.</i> ,)	Case No. 20-12522 (JTD)
)	
Debtor.)	
_____)	Re: Docket No. 2165

ORDER

For the reasons stated on the record at the hearing held on this day, the Debtors' First Omnibus Objection to Unsubstantiated Claims (Substantive) (D.I. 2165) is sustained.

SO ORDERED.

Dated: July 23rd, 2021
Wilmington, Delaware


JOHN T. DORSEY
UNITED STATES BANKRUPTCY JUDGE

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re

MALLINCKRODT PLC, *et al.*,¹

Debtor.

Chapter 11

Case No. 20-12522 (JTD)

(Jointly Administered)

Re: D.I. 3405, 3406

NOTICE OF APPEAL

PLEASE TAKE NOTICE that Attestor Limited, on behalf of itself and its affiliated entities, including Avon Holdings I, LLC (“Attestor”), and Humana, Inc. (“Humana”, and together with Attestor, the “Acthar Insurance Claimants”), creditors in the above-captioned chapter 11 cases, hereby appeal to the United States District Court for the District of Delaware, pursuant to 28 U.S.C. § 158(a) and Rules 8002(a)(1) and 8003 of the Federal Rules of Bankruptcy Procedure, from the order (D.I. 3406) (the “Order”) sustaining the *Debtors’ First Omnibus Objection to Unsubstantiated Claims (Substantive)* (D.I. 2165), entered on July 23, 2021, by the United States Bankruptcy Court for the District of Delaware, and the oral bench ruling issued in connection with the Order (the “Bench Ruling”), as so ordered at D.I. 3405.²

¹ A complete list of the Debtors in these chapter 11 cases may be obtained on the website of the Debtors’ claims and noticing agent at <http://restructuring.primeclerk.com/Mallinkrodt>. The Debtors’ mailing address is 675 McDonnell Blvd., Hazelwood, Missouri 63042.

² Attestor entered into an agreement with Humana to pursue and participate in any proceeds of Humana’s claims against the Debtors with respect to the distribution, marketing, and sale of Acthar. *See* Verified Statement of Willkie Farr & Gallagher LLP and Morris, Nichols, Arsht & Tunnell LLP Pursuant to Rule 2019 of the Federal Rules of Bankruptcy Procedure, D.I. 2066. Attestor is also the transferee and owner of additional Acthar-related claims subject to the Order and Bench Ruling, which were filed by United Healthcare Services, Inc. (“United”) and OptumRx Group Holdings and OptumRx Holdings, LLC (together, “OptumRx”). *See* Transfer/Assignment of Claim, D.I. 2317. For the avoidance of doubt, this notice of appeal includes all of the aforementioned claims.

PLEASE TAKE FURTHER NOTICE that a copy of the Order is attached hereto as **Exhibit A** and copies of the Bench Ruling and the so ordered docket entry are attached hereto as **Exhibit B**.

PLEASE TAKE FURTHER NOTICE that the names of all parties to the Order and Bench Ruling appealed from and the names, addresses, and telephone numbers of their respective attorneys are as follows:

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Dated: July 28, 2021
Wilmington, Delaware

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Matthew B. Harvey

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Exhibit A

Order

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**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:)	Chapter 11
)	
MALLINCKRODT PLC, <i>et al.</i> ,)	Case No. 20-12522 (JTD)
)	
Debtor.)	
_____)	Re: Docket No. 2165

ORDER

For the reasons stated on the record at the hearing held on this day, the Debtors' First Omnibus Objection to Unsubstantiated Claims (Substantive) (D.I. 2165) is sustained.

SO ORDERED.

Dated: July 23rd, 2021
Wilmington, Delaware

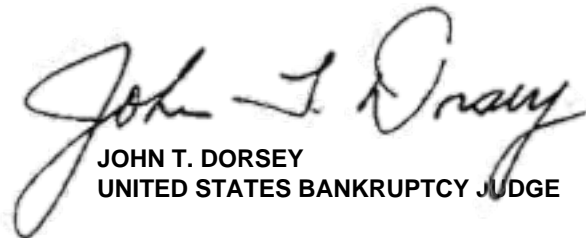

JOHN T. DORSEY
UNITED STATES BANKRUPTCY JUDGE

Exhibit B

Bench Ruling and Docket Entry

UNITED STATES BANKRUPTCY COURT
DISTRICT OF DELAWARE

IN RE: Chapter 11
MALLINCKRODT PLC, *et al.*, Case No. 20-12522 (JTD)
Courtroom No. 5
824 North Market Street
Wilmington, Delaware 19801
Debtors. July 23, 2021
9:03 A.M.

TRANSCRIPT OF TELEPHONIC HEARING
BEFORE THE HONORABLE JOHN T. DORSEY
UNITED STATES BANKRUPTCY JUDGE

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1 MATTERS GOING FORWARD:

2 7. [SEALED] Debtors' Motion to Quash (A) Ad Hoc Acthar Group's
3 Notice of Deposition of Melissa Falconi and (B) Ad Hoc Acthar
4 Group's Notice of Deposition of Hugh M O'Neill [Docket No.
5 3289 - filed July 20, 2021]

6 8. Ad Hoc Acthar Group's Motion to Compel Discovery and
7 Response to Debtors' Motion to Quash [Docket No. 3385 - filed
8 July 22, 2021]
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1 (Proceedings commence at 9:03 a.m.)

2 THE COURT: Good morning, everyone. This is Judge
3 Dorsey. We're on the record in Mallinckrodt PLC, Case Number
4 20-12522.

5 For those who haven't seen this before, this is
6 the new look for our Zoom calls. This is in anticipation of
7 getting ready to go back to live hearings, but because we
8 will continue to use Zoom instead of CourtCall even when we
9 have live hearings, this is how things will look going
10 forward.

11 So, with that, I'll turn it over to debtors'
12 counsel to run the agenda.

13 MR. MERCHANT: Thank you, Your Honor. Michael
14 Merchant of Richards, Layton & Finger on behalf of the
15 debtors.

16 Your Honor, before turning to the agenda, I
17 believe Mr. Alberto sent chambers an email on July 15th,
18 relating to an agreement with respect to payments pursuant to
19 the KEIP order, and the OCC wanted to make certain statements
20 on the record regarding that agreement. So, if acceptable to
21 the Court, I'd like to turn the podium over to Mr. Preis to
22 make those statements now, and then Mr. Klidonas will then be
23 making a brief statement on behalf of the debtors.

24 THE COURT: All right. Mr. Preis, go ahead.

25 MR. PREIS: Good morning, Your Honor. This is

1 Arik Preis from Akin Gump. Can you hear me?

2 THE COURT: I can, thank you.

3 MR. PREIS: Okay. I like the new look.

4 Good morning, Your Honor. Arik Preis, Akin, Gump,
5 Straus, Hauer & Feld, LLP on behalf of the Official Committee
6 of Opioid Related Claimants.

7 Your Honor, as agreed with the debtors, the OCC
8 wanted to take a few minutes at the outset of the hearing to
9 update the Court with regard to the KEIP. My remarks will be
10 (indiscernible) into four parts:

11 First, a reminder of what the KEIP order stated
12 with regard to our investigation (indiscernible)

13 Second, a brief summary of what we have done to
14 date.

15 Third, a very brief overview of what we've
16 preliminarily found.

17 And fourth (indiscernible)

18 THE COURT: Mr. Preis.

19 MR. PREIS: (Indiscernible)

20 THE COURT: Mr. Preis --

21 MR. PREIS: Yes.

22 THE COURT: -- you're breaking up a little bit on
23 your presentation. You're skipping out a little bit. I
24 think your voice is dropping and it's not picking up on the
25 microphone, maybe.

1 MR. PREIS: Oh, okay. Oh (indiscernible) is that
2 any better?

3 THE COURT: That's better.

4 MR. PREIS: Okay. Okay. I promise this
5 presentation will not take more than five minutes.

6 First, a reminder of what is in the KEIP order.
7 In accordance with Paragraph 4 of the KEIP order, the OCC and
8 the debtors agreed that the OCC would conduct (indiscernible)
9 investigation to the 12 individuals who are part of the KEIP.
10 In connection with the investigation, the debtors would
11 review and, as appropriate, produce up to an additional
12 50,000 (indiscernible) in other words, in addition to the
13 documents that we're already producing under our Rule 2004
14 investigation, that were specifically targeted to the
15 individuals in the KEIP.

16 The debtors also agreed to produce privilege logs
17 and witnesses for deposition (indiscernible) our
18 investigation, subject to the debtors' right to object to any
19 such deposition. In return, we agreed to inform the debtors
20 of any facts we found that would lead us to believe that the
21 KEIP participants engaged in wrongdoing that might
22 (indiscernible) by us to withhold (indiscernible) KEIP
23 payment.

24 We were also permitted, by agreement and in the
25 order, that, by no later than July 15th, which was obviously

1 last week, in our discretion, to file a motion to enjoin any
2 future payment and/or claw back any Q4 2020 payments
3 previously made to KEIP participants under the 2020 KEIP,
4 based on any findings that we uncovered in our investigation.

5 Those rights, which are under Paragraph 4 of the
6 KEIP order, are in addition to those in Paragraph 3 of the
7 KEIP order, which states that, under certain circumstances,
8 KEIP participants are not eligible to receive any
9 (indiscernible) payments and that all parties' rights are
10 reserved to seek disgorgement of previous payments under
11 certain circumstances.

12 As everyone knows, as Your Honor knows, we didn't
13 file anything on July 15th, but instead, we decided to
14 continue our investigation in light of the items I'm going to
15 mention in a moment.

16 We also, of course, reserve our rights under
17 Paragraph 3 of the KEIP order, as well as our right to object
18 to the debtor (indiscernible) releases being sought pursuant
19 to the proposed plan, some of the KEIP (indiscernible)

20 Okay. Second, our investigation. Although we
21 have vigorously pursued our investigation of potential
22 misconduct by the KEIP participants over the past few months,
23 that investigation was not complete by July 15th, nor could
24 it be. Although the debtors, to their credit, have produced
25 a significant amount of documents, the reason that the

1 investigation could not have been complete by July 15th was
2 that discovery was not complete by (indiscernible) for
3 instance, just yesterday, we received -- the debtors produced
4 more than 12,000 documents in response to our 2004 request.
5 And we understand that further productions are still
6 contemplated.

7 In addition, just one week before the July 15th
8 deadline, the debtors produced approximately 37,000
9 documents. It was obviously impossible to review and
10 consider that information before July 15th. That production
11 included (indiscernible) specific communications that the
12 debtors had previously withheld as privileged, but had
13 downgraded.

14 Moreover, we have found that many documents that
15 the debtors produced in response to our 2004 investigation
16 have been important in our analysis of the debtors' practices
17 concerning opioids and (indiscernible) analysis of the KEIP.

18 As of July 15th, the debtors had also not
19 completed production of privilege logs the OCC needs to
20 analyze in connection with our investigation. While the
21 debtors, to their credit, again, provided certain interim
22 privilege logs, metadata logs in response to our requests for
23 information on a rolling basis, the metadata logs lacked
24 standard information, the basis of which (indiscernible)
25 withheld.

1 Furthermore, the majority of the log documents --
2 or the log information, including several thousand entries
3 involving KEIP participants, was provided just days before
4 July 15th.

5 In addition -- and this, again, we -- is by
6 agreement -- no depositions have taken place yet, which makes
7 sense, given that the debtors' document production is not
8 complete. The debtors have been adamant that the
9 (indiscernible) witnesses be the (indiscernible) to
10 understand (indiscernible) all parties and all subject
11 matter. And the Court recently entered a confirmation
12 schedule and protocol calling for fact witnesses to continue
13 through August 13th.

14 We agreed to the July 15th deadline back in April,
15 when the OCC anticipated that all the debtors' document
16 production would be substantially completed in June, with
17 depositions to be completed (indiscernible) in July, in
18 anticipation of a confirmation hearing in August. That was
19 the schedule back then. Obviously, that's not
20 (indiscernible) anymore.

21 In light of the shifting time line, in early July,
22 the OCC, we reached out to the debtors, described what we had
23 found to date, and to seek an extension of the time to
24 complete our investigation and potentially file a motion.
25 The debtors refused, which was fine. Notwithstanding this

1 refusal and given that our investigation is still ongoing, we
2 made the determination not to file a motion on July 15th, but
3 to reserve our rights (indiscernible)

4 Third, a very, very brief update as to what we
5 have found to date. And we've conveyed this update, both
6 orally and in writing and in much greater detail to the
7 debtors outside professionals, the outside professionals to
8 the governmental ad hoc group and their Attorneys General,
9 subject in each case to the terms of the protective order.

10 We've reviewed the documents and we believe some
11 of the documents raise concerns regarding some, but not
12 nearly all of the KEIP participants in connection with the
13 sale, marketing, and distribution of prescription opioids
14 (indiscernible) such conduct comes in the form of certain
15 (indiscernible) the marketing and sale of the debtors'
16 branded prescription opioid medication, as well as in the
17 monitoring of specific orders of the debtors' (indiscernible)
18 opioid products.

19 We believe the debtors' practices included the
20 targeting of doctors known to prescribe (indiscernible)
21 quantities of opioid pills and focus on achieving
22 prescription metrics and incentivizing sales reps
23 (indiscernible) we believe that the debtors and these
24 individuals engaged in these practices at a time when the
25 addictive properties of opioids were completely understood

1 and widely known.

2 While we believe that the documents discovered to
3 date raise significant concerns, we also recognize that our
4 investigation is not complete. As I noted, documents still
5 must be produced and reviewed and we still must depose
6 certain key participants to learn more. Filing a motion at
7 this time would be premature (indiscernible)

8 Finally, our next steps. In addition to
9 establishing whether grounds exist to claw back or enjoin
10 KEIP payments, the investigation will establish whether we
11 have a basis to object to the proposed releases that the
12 debtors are proposing to offer (indiscernible) at the
13 appropriate time, and if we determine that doing so is in the
14 best interests of the opioid defendants, we will raise these
15 issues.

16 That's the extent of our statement. I understand
17 that the debtors would like to make some statements, as well.
18 But before we do that, do you have any questions for me?

19 THE COURT: No questions. Thank you, Mr. Preis.

20 MR. PREIS: Thank you.

21 THE COURT: Who is speaking on behalf of the
22 debtors? I'm sorry, I forgot. Mr. Klidonas, go ahead.

23 MR. KLIDONAS: Good morning, Your Honor. George
24 Klidonas of Latham & Watkins on behalf of Mallinckrodt PLC
25 and its affiliated debtors.

1 The debtors' professionals, as Mr. Preis
2 mentioned, have discussed with the OCC their preliminary
3 findings and the relevance of such preliminary findings on
4 the key employee incentive plan or the "KEIP," as we call it,
5 and the releases proposed under the Chapter 11 plan. But the
6 debtors do feel compelled to respond to the OCC's statement.

7 First, the debtors have fully participated and
8 continue to fully participate in the discovery process with
9 the OCC. We've worked as quickly as possible to produce
10 documents to the OCC. That said, the debtors, as mentioned
11 earlier, did not agree to the OCC's request to extend their
12 deadline to file a motion under the KEIP order because the
13 requested extension would not -- would have been after the
14 payment of the first half of the 2021 keep. And our position
15 is those payments should be made when the company is
16 obligated to make those payments.

17 Regarding the substance of the OCC statement, the
18 debtors disagree with the OCC's interpretation of the small
19 set of documents that they provided, about 60 that they
20 showed us. Many of these documents have already been
21 produced to the states and other multi-district litigation
22 plaintiffs; and, therefore, these same allegations were
23 raised pre-petition in a variety of different complaints.

24 The company has defended those pre-petition
25 allegations vigorously in the past and the proposed opioid

1 settlement resolves all of those claims and allegations in
2 their totality. The debtors believe that conflating the
3 entitlement to KEIP payments is really sort of a veiled
4 attempt at calling into question the entire settlement
5 reached and the releases set forth in the plan.

6 If what the OCC wants to do is re-litigate these
7 allegations that have been settled, then debtors believe that
8 the proposed opioid settlement could have the potential of
9 unraveling. But we decided, on balance, having a fight on
10 this issue right now would just be a complete waste of estate
11 resources and addressing confirmation of related issues in a
12 vacuum this early would just be unproductive.

13 To put this into context, the debtors believe that
14 the OCC's preliminary findings regarding the actions of a
15 small subset of KEIP participants -- as of today, our
16 understanding, it's about three of them -- and certain
17 aspects of the monitoring and marketing practices are
18 generally misguided.

19 The documents raised by the OCC are about from
20 2011 to 2015, when the companies produced and sold the
21 branded pain products. We believe that Mallinckrodt branded
22 pain medication never made up more than about .5 percent of
23 the opioid pain market. In addition, the debtors contend
24 that every Mallinckrodt pain product was FDA approved, every
25 milligram of such product and distributed was and is

1 authorized in advance by the DEA and then reported back to
2 the DEA in accordance with compliance protocols.

3 The debtors also believe and contend that the
4 purpose of the branded opioid marketing strategy was to
5 inform prescribers of the benefits of its longer lasting,
6 extending relief pain products, that serve generally as an
7 alternative, to allow patients to take these medications less
8 frequently.

9 And finally, with respect to the SOM -- the
10 suspicious order monitoring -- Mallinckrodt's historical
11 controls have been lauded by the DEA as exemplary and
12 consistent with what the DEA expects for Mallinckrodt as an
13 industry leader. But as Mr. Preis mentioned, you know, just
14 as the OCC is continuing its review, we, the debtors -- you
15 know, the investigations being conducted by the independent
16 directors, more specifically, in connection with the plan
17 releases are still ongoing and are assessing the conduct that
18 the OCC is alleging.

19 So the last point I just want to raise on
20 discovery, Your Honor, is we just want to sort of clarify the
21 record a little bit. The OCC has been the beneficiary of
22 extensive discovery in these Chapter 11 cases. As of July
23 14th, the OCC has received 95 percent of the documents
24 responsive to their requests. The vast majority of these
25 were produced by the end of June.

1 The negotiated discovery with respect to the OCC's
2 KEIP review was produced by the end of April, as contemplated
3 by the KEIP order.

4 And then I think it was mentioned earlier, interim
5 privilege logs have been provided and metadata for all
6 privileged documents was sent while the final privilege logs
7 are being completed.

8 And no depositions have been sought or noticed in
9 connection with the KEIP to date, nor was there any discovery
10 about any documents found by the OCC until almost two months
11 after the KEIP (indiscernible) was provided.

12 So, just to circle back and close the loop, you
13 know, neither the OCC, nor the debtors, as we both mentioned,
14 are looking to have this argument today on these issues. We
15 both felt the need to at least provide the Court with some
16 context and with their perspectives of where things stand.

17 With that, Your Honor, I think we can turn to the
18 agenda today.

19 THE COURT: All right. Thank you, Mr. Klidonas.

20 MR. KLIDONAS: You're welcome.

21 THE COURT: Mr. Merchant, back to the agenda.

22 MR. MERCHANT: Yes, Your Honor. Turning to the
23 agenda, I think, based on the dialogue with chambers this
24 week, it probably makes sense to turn to Agenda Items 7 and 8
25 first, which are the discovery-related motions related to the

1 unsubstantiated claims objection going forward today. So,
2 with that, I'll cede the podium to Mr. Murtagh to address the
3 debtors' motion to quash.

4 THE COURT: Mr. Murtagh.

5 MR. MURTAGH: Good morning, Your Honor. It's Hugh
6 Murtagh from Latham & Watkins on behalf of the debtors. Can
7 you hear me okay?

8 THE COURT: Yes, thank you.

9 MR. MURTAGH: Your Honor, I'll lay out where I
10 think we are on discovery disputes and then tell you how I
11 plan to go through it, subject to the Court's approval. My
12 understanding based on the filings by the Ad Hoc Acthar Group
13 yesterday are as follows:

14 We have a live motion to quash as to depositions
15 noticed for Mr. O'Neill and Ms. Falcone. I don't believe the
16 Ad Hoc Acthar Group is continuing to press requests for a
17 deposition of Ms. Falcone. So, as to the motion to quash, I
18 will focus on the request to depose Mr. O'Neill.

19 The Ad Hoc Acthar Group also filed its motion to
20 compel production of certain documents, and that remains
21 open. And I understand that's a portion of the motion to
22 compel. But if it's more expedient for Your Honor, I'll
23 address that also while I'm addressing the motion to quash
24 Mr. O'Neill's deposition.

25 THE COURT: Yeah, let's do them all at once.

1 MR. MURTAGH: Okay, Your Honor.

2 Your Honor, the headline on all of this is that
3 these discovery requests are months late, irrelevant, and
4 unnecessary. The background, as Your Honor knows, is that
5 the debtors filed their objection to the Ad Hoc Acthar
6 Group's claims nearly three months ago, on April 30th. And
7 as Your Honor also knows, we had a discovery dispute at that
8 time about the scope of discovery in this matter and Your
9 Honor made a ruling on the proper scope of discovery in this
10 matter.

11 The debtors, thereafter, provided extremely broad
12 discovery to the ad hoc group and also provided additional
13 new discovery with targeted responses to questions asked,
14 relating specifically to the subject matter here, which is
15 substantiation for what we view as the unsubstantiated
16 claims.

17 Thereafter, Your Honor, the ad hoc group had the
18 opportunity to file two responses, and the second came over
19 two months after the filing of the objection. The ad hoc
20 group never, until last Friday, weeks after the filing of
21 their second response and a week after the debtors' reply,
22 even suggested that it had insufficient discovery.

23 Now the ad hoc group asserts that the debtors'
24 reply somehow revealed to them an urgent need to depose Mr.
25 O'Neill and to receive more documents. And they appear to

1 give two reasons, neither of which is persuasive, and I'll go
2 through each of them, first dealing with Mr. O'Neill.

3 The first reason they give is that our reply
4 somehow alerted them to the existence of a publicly reported
5 opinion issued two years ago in the opioid MDL litigation.
6 And in respect of that opinion, the ad hoc group argues that
7 this belated discovered opinion is important because, first,
8 it allegedly validates an alter ego theory of liability
9 against PLC, and second, that Mr. O'Neill's testimony is
10 critical to that supposed validation. Well, neither of those
11 assertions is true, Your Honor.

12 First, to be clear, the opinion states only that
13 the parties dispute and offer conflicting evidence on alter
14 ego and the matter should be litigated at a later date. And
15 that later litigation never occurred.

16 The second is that Mr. O'Neill's name is not even
17 mentioned anywhere in the opinion.

18 So, apparently, on this, what the ad hoc group has
19 in mind is a statement in the plaintiffs' brief that Mr.
20 O'Neill did not recall details about certain Mallinckrodt
21 entities' board composition. But Your Honor, on this
22 supposed reason for deposing Mr. O'Neill, if the ad hoc group
23 had wanted to explore alter ego theories and board
24 composition, they could have done so over the last three
25 months. They could have sought additional discovery. They

1 could have asked questions of Mr. Welch in deposition, and
2 they can attempt to do so with Mr. Welch on the stand today.
3 They do not need Mr. O'Neill for that. So the belated
4 discovery of the MDL opinion and Mr. O'Neill's supposed
5 importance to it is not a grounds for deposing Mr. O'Neill.

6 The second reason that the ad hoc group has given
7 for deposing Mr. O'Neill is that he has allegedly become
8 relevant because his name appears on a single document cited
9 in the debtors' reply. That document is a board deck
10 discussing Mallinckrodt Pharmaceutical International -- sorry
11 -- Mallinckrodt Pharmaceutical Ireland Limited's decision-
12 making responsibilities with regard to Acthar. And it was
13 produced to Rockford pre-petition and it was offered in the
14 brief to demonstrate that the ad hoc group had notice pre-
15 petition of the involvement of Mallinckrodt Pharmaceuticals
16 Ireland Limited with Acthar.

17 It does not make relevant anything Mr. O'Neill did
18 or said. The only connection between that document and Mr.
19 O'Neill is that his name appears I believe on an email cover
20 sheet to the transmission of the document, that's it. So,
21 having not made Mr. O'Neill irrelevant in any way, in any new
22 way in the reply, this supposed second reason, his name is
23 mentioned as a name attached to a document, also is not a
24 reason to depose Mr. O'Neill.

25 And with regard to the deposition of Mr. O'Neill

1 in general, before turning to the RFPs, Your Honor, the
2 bottom line is that the ad hoc group has repeatedly noticed
3 Mr. O'Neill for deposition in these cases on what appears to
4 be tactical grounds, and this is no different. I believe
5 this is the third time they've done so. And now it appears
6 to be an attempt to disrupt a hearing that's been three
7 months in the making. And the delay in the timing on this is
8 inexcusable and the deposition is wholly unnecessary.

9 With regard to the RFPs, Your Honor, the story is
10 much the same. They are also inexcusably late, irrelevant,
11 and unnecessary. Nevertheless, to be clear, in an attempt to
12 avoid having a dispute before the Court, Your Honor, the
13 debtors agreed to produce documents responsive to several of
14 the requests and responsive to the requests on which we
15 thought the ad hoc group was focused.

16 So, specifically, the debtors agreed to production
17 of the O'Neill deposition in the 2019 opioid MDL proceedings
18 and all exhibits, and also the entire record of the
19 jurisdictional motion to dismiss dispute in that litigation,
20 on which the ad hoc group is focused, and they now have those
21 documents.

22 We also responded and made clear that all of the
23 support -- all of the documents supporting our reply are
24 attached to our reply. So that took care of three of the
25 requests, Your Honor. And we maintained objection to four of

1 the requests.

2 Now one of those requests is for all of the
3 documents used to prepare Mr. O'Neill for his deposition in
4 2019. And we object on the basis that that is work product
5 and attorney/client privilege and not subject to production.
6 The remaining three requests, Your Honor, are hopelessly
7 over-broad and burdensome, in addition to being irrelevant
8 and inappropriate. And what they comprise, Your Honor, is a
9 request for all communications, documents, agreements and any
10 other material relating to Acthar by, with, or about 32
11 different Mallinckrodt entities from the beginning of time to
12 today.

13 Now, plainly, that request is hopelessly over-
14 broad. But even if it were more limited, the request would
15 still be hopelessly late and made without any attempt to
16 discern whether there's a specific need or any documents that
17 are sought are already in the voluminous productions that
18 have been made to the Ad Hoc Acthar Group.

19 So, much like the request to depose Mr. O'Neill,
20 Your Honor, the -- these requests have no basis to be made
21 now. They're made without considering whether the
22 information the ad hoc group requests is actually relevant or
23 needed or even in their possession already. And it appears
24 to be another attempt to insert a tactical delay into these
25 proceedings. And in short, Your Honor, the time for this is

1 up, and the time to litigate these issues is now, on the full
2 and complete opportunity and record that have been made over
3 the last three months.

4 THE COURT: Okay. Thank you, Mr. Murtagh.

5 Let me hear from the ad hoc group.

6 MR. ASTIN: Good morning, Your Honor. Daniel
7 Astin for Ciardi, Ciardi & Astin. My co-counsel Mr. Haviland
8 will be presenting this morning. And we thank the Court for
9 accommodating us this early, before the regularly scheduled
10 hearing.

11 THE COURT: Mr. Haviland, go ahead.

12 MR. HAVILAND: Good morning, Your Honor. It seems
13 to me that the debtors' objections and motion bases for both
14 the depositions and the documents are three: The discovery
15 is late, it's irrelevant and unnecessary. I don't know where
16 the third prong comes in the rules, other than Rule 26 up to
17 Rule 37, so I'll focus on the timing and the relevancy
18 arguments.

19 I have to give a little context, Your Honor, so
20 you can understand how this dispute came about. The debtors
21 have known about the Acthar Plaintiffs' desire to take Steve
22 O'Neill's -- or Hugh O'Neill's deposition since prior to the
23 bankruptcy. You'll recall the first time we met, Your Honor,
24 was on an emergent basis to quash the court-ordered
25 deposition of Mr. O'Neill out of the Rockford Court.

1 The debtors prevail upon the Court, saying that
2 they needed a breathing spell, and that Mr. O'Neill and Mr.
3 Trudeau were critical to the reorganization function. I
4 remember Mr. Stearn arguing for an hour at the end of that
5 hearing, only to have it resolved with the Court directing
6 the parties to meet and confer to schedule that deposition.
7 And we've attempted to do that -- and Mr. Astin can attest --
8 multiple times over the last ten-plus months, and never once
9 have the debtors offered to provide a deposition date for Mr.
10 Trudeau or Mr. O'Neill.

11 So the context is important. We had court-ordered
12 deposition dates coming into this bankruptcy. The debtors,
13 in the personages of Mallinckrodt PLC and ARD had filed
14 motions to quash for Apex Protection, and they were denied on
15 a full record by a Federal Judge.

16 And the reason why this issue has come to the fore
17 today, Judge, is we got a reply brief after hours on July
18 9th, a Friday night. It was almost 50 pages, well beyond the
19 page limit provided under the rule. The Court granted leave
20 to the debtors to put that volume before the Court. And in
21 that volume -- on a reply, mind you, this is a reply to the
22 response to their objections -- they proceeded down a number
23 of paths that weren't raised in the initial objection, and
24 that's why this is important. There's nothing late about
25 inquiring about a position of the debtors that's newly framed

1 in a fifty-page filing on reply.

2 Now we noticed Mr. O'Neill's deposition last
3 Thursday. We asked -- and we also noticed his one-time
4 executive assistant, Melissa Falcone, who then become a Vice
5 President of Patient Services, and we now know through Arnold
6 & Porter is no longer with the company. And I point that
7 out, Judge, because, last Friday, Arnold & Porter
8 represented, on behalf of the debtors, they don't represent
9 Ms. Falcone. She's a former executive employee. I have an
10 email at four o'clock last Friday to that effect:

11 "Don, Ms. Falcone left the company shortly after
12 you deposed her in February 2020, we do not currently
13 represent her."

14 The debtors have not demonstrated to this Court
15 how they have a right to move for a protective order on a
16 former employee. And when we got that notice, Judge, we
17 expedited a subpoena. And you'll see in our filings, we
18 provided not one, but two affidavits of service of Ms.
19 Falcone in Illinois, where she currently resides, at her
20 place of business, at AbbVie, and her home address.

21 So, since the time of service, last Friday, we
22 haven't heard from Ms. Falcone or counsel. All we heard from
23 the debtors was they don't represent her. So they have a
24 procedural problem in saying that they can quash a subpoena
25 of a former employee more than a hundred miles from this

1 Court.

2 And realizing that it was more than a hundred
3 miles, we issued the subpoena under the Northern District of
4 Illinois caption, the Rockford case, so that that court would
5 have jurisdiction over any discovery disputes. I'm not
6 suggesting Your Honor doesn't, but we hadn't heard from the
7 debtors at all until late in the day, when they filed the
8 motion for a protective order on Wednesday, taking this
9 position. There's a fundamental problem with their approach
10 in trying to prevent Ms. Falcone's deposition, and I'll get
11 to the relevancy in a moment.

12 But as further background, the Court should also
13 understand that the Ad Hoc Acthar Group has produced four,
14 four clients for depositions: The City of Rockford; this
15 Acument Global Technologies, whose designee sits as the chair
16 of the committee; Teamsters Local 830; and Dakota County,
17 Nebraska. Four. We also produced an expert for deposition.
18 That's five depositions.

19 The debtors have yet to produce one executive for
20 deposition. Mr. Welch, who I see -- good morning, Mr. Welch
21 -- we've had the opportunity to depose him too many times.
22 I'm sure he's tired of it; we are, as well. He seems to be
23 their go-to witness. And I credit him for his ability to try
24 to answer questions. But Judge, he worked in the specialty
25 generics division of the company.

1 Mr. O'Neill is the Executive Vice President of
2 Commercial Operations of the brand business. And what you're
3 going to hear about today in the hearing is whether or not
4 we're entitled to claim against entities in the brand
5 business.

6 Now the reason why we looked to see whether there
7 had been any issue involving alter-ego was because in those
8 notices I just referenced the debtors asked my clients, at
9 request number nine, all the basis for a theory of alter-ego.
10 And it caused plaintiff's counsel to scratch heads saying why
11 are they asking this question. It seems like they know
12 something we don't.

13 Sure enough we look and we see Judge Dorsey -- I'm
14 sorry, you're Judge Dorsey -- Judge Polster -- I'm a little
15 tired, Your Honor, it's a Friday -- in the City of Summit
16 case, the In Re National Opioid Litigation, 2019 ruled on a
17 similar motion by Mallinckrodt PLC seeking to prevent its
18 jurisdiction in conjunction with two subsidiaries, the SpecGx
19 generic company and then an entity by the name of
20 Mallinckrodt LLC which the debtors say is a generic company;
21 we have evidence to say that it's a brand company. It signed
22 contracts on behalf of the Acthar business. So that is a
23 factual dispute.

24 We're only getting to the issue of whether or not
25 we can avail ourselves of the same theory that the generic

1 opioid plaintiffs have viewed. And in the ruling by Judge
2 Polster he found, and I'm at star of the Lexus case 92, the
3 court finds that the issue of whether SpecGx LLC and/or
4 Mallinckrodt LLC are the alter-egos of Mallinckrodt PLC
5 should be litigated in the track one trial. Mr. Murtagh says
6 it was kicked down the road. No, the judge found enough
7 evidence of alter-ego and it was evidenced.

8 Here is the problem, Judge, everything was filed
9 under seal. We asked the debtors will you give us that
10 material so we can understand the basis of the ruling. They
11 said -- well, they didn't respond initially. They eventually
12 had us go back to plaintiff's counsel (indiscernible), we
13 did. We needed their consent to have those under seal
14 pleadings and documents produced. We finally just got them
15 the other day. In fact, late yesterday. We added them to
16 our exhibit list.

17 Counsel is right that Judge Polster doesn't detail
18 the evidence because it was under seal and counsel is correct
19 that plaintiff's counsel, in their brief, repeatedly cited to
20 the deposition transcript of the head of commercial
21 operations, Mr. O'Neil. And why it's evidentiary here,
22 Judge, and why his deposition here is so critical the senior
23 most person in charge of the entire brand side business said
24 I don't differentiate companies. To me it's Mallinckrodt,
25 its Mallinckrodt Pharmaceuticals. I don't know who pays my

1 check, I don't think PLC, LLC, any subsidiary company, I am
2 in charge of all of it; operations are mine. I make those
3 decisions.

4 We put that transcript before the court for later,
5 but, Judge, that is just a snapshot of the issue that the
6 debtors are presenting to the court. Now remember it's the
7 debtor's objecting to our claims against entities like
8 Mallinckrodt LLC who signed contracts. That is why the
9 ruling by Judge Polster is so important because LLC is also
10 on the generic side business in opioids and the judge there
11 said that goes to trial.

12 Now I'm not going to pre-argue today's issues, but
13 that is the backdrop of what began in October with Mr. O'Neil
14 has continued since came to a head this past week and last
15 week because of the importance of his deposition.
16 Unbeknownst to us, but fully known by the debtors who were
17 litigating over the opioid litigation.

18 Now we also know that Arnold & Porter has
19 represented Mr. O'Neill because at Exhibit 48 of our exhibits
20 today that we shared with Your Honor Arnold & Porter abruptly
21 adjourned Mr. O'Neil's deposition. It had been scheduled for
22 November citing that he had a problem and that he couldn't
23 appear. At some point the debtor has to put up a witness
24 other than Mr. Welsh. I'm sure Mr. Welsh will appreciate
25 that. I noticed, Judge, that others have noticed Mr. O'Neil,

1 the committees have noticed Mr. O'Neil.

2 The debtors are unwilling to negotiate a date,
3 they have been unwilling to talk about an omnibus schedule
4 for discovery. Mr. Astin has tried repeatedly to get there
5 to be an omnibus approach to discovery and not just plan
6 discovery, discoveries relating to our issues. When I say
7 our issues their objections, the objection today, but they
8 say you don't get them here because he's irrelevant and I
9 suppose we will hear weeks from now whether or not they're
10 going to produce him later.

11 Relevancy is not a grounds to quash a deposition
12 notice. Counsel has only argued relevancy and timing. I
13 have given you the timing. He's relevant. There is no one
14 more relevant than Mr. O'Neill when it comes to the
15 commercial operations of the brand side business. I think
16 Mr. Welsh would freely admit that if asked. So he should be
17 deposed, he should be asked -- forced to answer questions
18 about these distinct entities that the debtors are now
19 claiming for the first time have independence of the PLC.

20 Why that is important, Judge, and you probably
21 read this in the papers, they're now arguing this dual
22 position that in some senses they're a single entity, that
23 Mallinckrodt is Mallinckrodt. In response to the Humana
24 brief they raised the Copperweld antitrust decision which
25 says that a parent cannot conspire and agree with a

1 subsidiary. Well that is right, but they don't show the
2 court, and we will show the court later, that Copperweld was
3 further to say because it's a single enterprise because
4 there's a purpose between a parent and a sub, and that's why
5 you can't have a conspiracy between those entities.

6 The debtors are trying to do that now by saying
7 that somehow we had to sue every single disparate subsidiary,
8 but they never made that argument in Rockford. They never
9 made that argument 420. They never made that argument in
10 322. In fact, they never objected to our suing the PLC. I
11 note that they did object in the Human case, but not in our
12 case.

13 So we're being pushed to a point where now all of
14 a sudden the debtor is taking a completely different approach
15 and they're saying you don't get to depose the one witness
16 who can speak to that issue whether or not there's
17 independence of form, function, decision making of all these
18 disparate entities and the head of commercial operations
19 knows that better than anybody else.

20 The reason why it's important, Judge, is they put
21 it in their reply. They are arguing we should have known.
22 The Ad hoc Acthar group should have known better, should have
23 done more and all I'm going to cite to, Your Honor, is what
24 we put in the record (indiscernible) 147 through 162 is the
25 discovery in Rockford. We issued four sets of discovery. We

1 asked for all contracts, and this is important the defendants
2 and any third-party relating to distribution, pricing,
3 marketing, sales of Acthar. Repeatedly Mallinckrodt said
4 they complied.

5 The court ordered no less than three times
6 compliance. In ECF 171, 224 and 354 which are Exhibits 152,
7 153, and 154 of the evidence we put in. Court orders and
8 repeatedly they say we produced the documents. We propounded
9 the request last week to say, okay, to Mr. Murtagh's point.
10 If the record is what the record is and they did respond to
11 the one request give us all the evidence that supports your
12 reply. Mr. Murtagh responded you have it. Well then we said
13 we want to make sure we have all the evidence of the
14 discussions, the contracts, presentations, communications,
15 discussions of Acthar between the non-debtor entities.

16 The response is interesting, burden. Burdon
17 denotes we investigated, we've seen that it's too much, it's
18 too difficult. They haven't put an affidavit of burden
19 forward, that's why I couldn't discuss with Mr. Murtagh how
20 do we get past that objection. He didn't articulate to us.
21 He didn't say, Mr. Haviland, you have 100,000 pages of
22 documents is there some way we can give you (indiscernible)
23 to say, okay, this one speaks to all the other documents. We
24 never had that discussion. They simply say no. They say no
25 that it's irrelevant and burdensome. It's relevant because,

1 Your Honor, we did have that hearing on the motion to compel
2 and Your Honor said that we can follow the money and follow
3 the function. That is what we are trying to do.

4 When we got the reply and we see them putting
5 documents in from the Rockford litigation which are, frankly,
6 cherry-picked out of the record Ms. Falconi's emails, Mr.
7 O'Neil's emails, and then trying to ascribe some meaning to
8 that that we should have known that this ARD entity that we
9 sued under the parent, PLC, the entire form and function was
10 blown up and all the functions went to a UK company and an
11 Irish company.

12 Your Honor, no witness ever said that. We deposed
13 William Hillmer as a corporate -- well the FDC deposed him as
14 a corporate designee in 2016, that's 159. The corporate
15 designee of Mallinckrodt. He never said that. And by the
16 way, he was designated one month after this company adopted
17 the (indiscernible) process where they're having these two
18 foreign parents make decision making. Did he perjure himself
19 he certainly did tell the truth.

20 Then we deposed him later on July 21st, 2020. I
21 asked him, did you testify truthfully, that's Exhibit 162, he
22 said yes. Has anything changed; no. We deposed Ms. Falconi
23 February 28th, 2020, Exhibit 160, who do you work for;
24 Mallinckrodt Pharmaceuticals. That entity doesn't exist.
25 She was the right-hand to Mr. O'Neil. Never once did she

1 say, when asked about pricing distribution, Acthar, Mr.
2 Haviland, we go to Ireland. We have to get the Irish
3 company's approval.

4 Then we deposed Mike Close [phonetic], the
5 "closer" they call him, the contract guy, the guy actually
6 involved in all the contracts, not once did he ever say
7 here's what happens, by the way, that's Exhibit 161, we have
8 to go to Ireland and the UK to get approval for all pricing,
9 distributions, decision-making on Acthar. They are telling
10 us, through this court, that we failed in our job.

11 Your Honor, we have four sets of written
12 discovery, three court orders, fifteen depositions only four
13 of which are current employees of Mallinckrodt. We have got
14 the debtor moving repeatedly to prevent depositions starting
15 with Mr. O'Neil and continuing through today. The question
16 is when are we going to get due process, when are we going to
17 get the discovery.

18 These debtors want to have an objection where they
19 get to put Mr. Welsh up and say what they want him to say.
20 And I'm not suggesting that he's not testifying as an
21 informed witness for the company, but he doesn't have direct
22 personal knowledge of those issues. He's not on the emails.
23 He wasn't at the presentations. He's not part of those
24 organizations.

25 When are we going to get the discovery. Now I'm

1 not suggesting that we adjourn today. I think we use today.
2 But I am suggesting we can't close, not with the record the
3 way it is as created by these debtors.

4 Thank you.

5 THE COURT: Mr. Murtagh?

6 MR. MURTAGH: Yes, Your Honor. Just to try to
7 bring some clarity I don't understand Mr. Haviland to still
8 be requesting a deposition of Ms. Falconi and it was not made
9 part of the motion to compel. I didn't hear any reason why
10 he needs Ms. Falconi. So I am going to assume that that's
11 not part of the motion. I am going to leave Ms. Falconi out
12 of this for now. That would take care of one of the
13 disputes.

14 The second with regard to Mr. O'Neil's deposition.
15 I understand from Mr. Havilland, as he's told the court
16 repeatedly, that he would like an opportunity to examine Mr.
17 O'Neil. Mr. O'Neil will be put up for examination at the
18 beginning of August as part of plan confirmation. There are
19 many people who have an interest in deposing Mr. O'Neil and
20 there will be an opportunity to depose Mr. O'Neil.

21 There have been repeated occasions in this case in
22 which Mr. Haviland has done what he's done today which is to
23 say in the context of a separate specific matter it's unfair
24 that he has not been allowed to depose Mr. O'Neil. He, in
25 fact, had raised this question back in May and asserted, in

1 court, that he needed to depose Mr. O'Neil as part of his
2 response to the unsubstantiated claims objection. He later
3 left off of that and did not pursue it. That was over two
4 months ago.

5 This briefing commenced three months ago. When
6 Mr. Haviland did not say that I could follow him in his
7 argument was any reason why Mr. O'Neil has now become
8 relevant for the first time three months after these
9 objections were put in place. Again, Your Honor, the fact
10 that Mr. O'Neil was deposed in an MDL proceeding two years
11 ago and the proceeding, itself, are not new. They did not
12 become new in our reply and they were not referenced in our
13 reply.

14 We did not raise alter-ego for the first time in
15 our reply. As Your Honor knows, we have been arguing alter-
16 ego issues before this court for months in the context of
17 estimation, in the context of discovery disputes. It is not
18 a surprise to hear that the debtors want to know whether
19 there is any assertion of alter-ego because that could be a
20 ground on which claimants are attempting to create claims and
21 the as the debtors have said repeatedly believe those to be
22 estate causes of action. That is patent in the record for
23 months. So that is not new.

24 The single document about Mallinckrodt
25 Pharmaceuticals Ireland Ltd., having decision making

1 authority also is not new. The point of putting in the reply
2 was to demonstrate that Rockford had it prepetition. There
3 is just nothing new today, Your Honor. There is no reason
4 that has become apparent in the past week for a need to
5 depose Mr. O'Neil in the context of these proceedings.

6 If Mr. Haviland felt that he needed Mr. O'Neil to
7 defend his claims he had that need three months ago and the
8 time to argue about it was three months ago. He didn't and
9 he never asked for it. Today is the day of the hearing on
10 the objection. It's just inexcusable to be raising it at
11 this stage.

12 As I said at the beginning, Your Honor, that is
13 exactly the same for the RFP's. We gave the discovery after
14 discovery discussions before Your Honor that was ordered and
15 we have not heard for months that there is anything
16 insufficient about it. The new request is for, literally,
17 every document that exists relating to Acthar for all time
18 among thirty-three separate entities. It is not targeted at
19 all. It is just an attempt to disrupt.

20 These are both just attempts to disrupt and they
21 should be denied. The argument can proceed today and at the
22 close of today's hearing, if we can finish today, the record
23 and the argument on this proceeding should be closed. It's
24 been going on for three months.

25 THE COURT: Alright, well the only issue before me

1 today is the issue of whether or not the proofs of claim
2 filed by the ad hoc group and the insurance group of Acthar
3 claimants complies with the code, the rules, and the Third
4 Circuit's ruling in Allegheny. As Mr. Murtagh pointed out, I
5 did give leeway on taking discovery with regard to these
6 claims, as Mr. Haviland pointed out, to follow the money and
7 see where that took them.

8 The issues about whether or not -- well, let me
9 back up. I allowed that discovery because I was under the
10 impression that the Acthar claimants were going to seek to
11 amend their proofs of claim. For whatever reason they
12 decided not to do that. So the only thing I have before me
13 today are the proofs of claim and the only thing I'm going to
14 rule on today are whether or not those proofs of claim, as
15 written, state facts sufficient to allege a claim against the
16 debtors against whom those proofs of claim were filed.

17 I am not going to get into whether or not there is
18 other evidence that might have been used to -- that could
19 have been included in those proofs of claim because, again,
20 there is no motion to amend, so there is nothing for me to
21 decide on that issue. The only issue -- again, I am going to
22 make this very clear, the only issue before me today is are
23 the proofs of claim, as written, sufficient to state a claim
24 against the debtors against whom those proofs of claim were
25 filed.

1 This discovery may go to the question of whether
2 or not there could be an amendment to those proofs of claim,
3 but that issue is not before me. So we're going to get to --
4 I'm going to set this motion aside for now. We're going to
5 go to the underlying merits of the only substantive issue
6 before me which is the proofs of claim and we will go forward
7 from there, then I will make my ruling and we'll see whether
8 or not the additional discovery might be allowed somewhere
9 down the road. For now that issue is moot as far as I am
10 concerned.

11 MR. MURTAGH: Understood, Your Honor. Based on
12 your instructions just now do you mind if we take a moment or
13 two just to confer among our team on how to proceed?

14 THE COURT: Yes. We will take a ten minute
15 recess. We will reconvene at 10:05.

16 MR. MURTAGH: Thank you, Your Honor.

17 (Recess taken at 9:53 a.m.)

18 (Proceedings resumed at 10:05 a.m.)

19 THE COURT: We're back on the record. Mr.
20 Murtagh, are you ready to proceed?

21 MR. MURTAGH: Yes, Your Honor. I will go ahead
22 and turn the podium over to Mr. Harris.

23 THE COURT: Mr. Harris?

24 (No verbal response)

25 THE COURT: Mr. Harris, can you hear me?

1 MR. MURTAGH: Can you hear us?

2 (No verbal response)

3 MR. MURTAGH: He may have lost audio. Let me send
4 him a text.

5 MR. HAVILAND: Your Honor, before we begin, may I
6 be heard?

7 THE COURT: On what?

8 MR. HAVILAND: On the issue that came up toward
9 the end of the last session, the issue about leave to amend.
10 I am only offering a potential solution to a protracted
11 hearing today. In our brief, at Docket 2529, we requested
12 leave to amend at Pages 15 through 18. We would be willing
13 to forego any examination of Mr. Welsh today if the debtors
14 would agree to the admissibility of the documents that were
15 produced and that are part of our file.

16 That would, at least, make the issue more acute
17 for the court. Of course, those documents are not attached
18 to our proof of claim; only the complaints were. We do point
19 out in our opposition to the objections we're seeking leave
20 to amend through this process to put the factual detail
21 before the court. I'm suggesting that that is a way to short
22 change today not to take away anyone's ability to present
23 evidence, but I am going to suspect that Mr. Welsh hasn't
24 seen a number of the documents and the examination is going
25 to be lengthy.

1 If the debtor is amenable to the admission of
2 those exhibits they're in the court file and we can move onto
3 the next issue of whether or not (indiscernible).

4 THE COURT: I'm not sure if Mr. Harris heard all
5 of that.

6 MR. HARRIS: I'm sorry, Your Honor, I was having
7 audio problems. I apologize, I did not.

8 THE COURT: Mr. Haviland, do you want to repeat
9 that?

10 MR. HAVILAND: Sure. I'm sorry, Chris, I didn't
11 realize you were out. Mr. Harris, I just said to the court
12 that as a point of order, based on the court's observations
13 of the issues before the court today in terms of the existing
14 proofs of claim, the existing proofs of claim, as everyone
15 knows, at least for the ad hoc Acthar group, consist of an
16 addendum which describes the claims, a complaint which talks
17 about the conduct of the named defendants, the PLC and ARD,
18 and unnamed co-conspirators and others, then it provides, as
19 Exhibits B and C, the damages claim and the actual proof that
20 the claimant is included in the claim within the complaint.

21 None of the exhibits that we're about to examine
22 Mr. Welsh on, as a corporate designee, are included in the
23 proofs of claim. It seems to me the court has framed the
24 issue, and I'm not suggesting that Judge Dorsey has done
25 anything other than set the pace of play for today, we have a

1 number of exhibits, as you can see from our exhibit list,
2 that are not in our proofs of claim. The issue is whether
3 they should be and if so when.

4 In our opposition brief I just pointed out that
5 its filed May 21st at Docket 2529 beginning on Page 15 of 19
6 we say leave to amend the proofs of claim should be granted.
7 We cite Federal Rule of Civil Procedure 15(d), we cite cases
8 in the Third Circuit and the District of Delaware that leave
9 to amend should freely be given. That was two months ago.
10 We haven't gotten leave to amend and we would like leave to
11 amend. And we are willing to forego any examination of Mr.
12 Welsh today provided that the debtors agree to the
13 admissibility in this record today of the documents that we
14 put in that are Mallinckrodt documents that were produced
15 either in the context of the bankruptcy, which most of them
16 are, or some which come from the underlying Rockford file and
17 that is why they haven't made publicly available.

18 This is going to be a long hearing today. It
19 seems to me that that is the issue before the court whether
20 or not leave to amend should be granted.

21 MR. MCCALLEN: Your Honor, may I be heard on that
22 briefly?

23 THE COURT: Your cross talking here. Who -- let
24 me -- was it Mr. McCallen? Go ahead.

25 MR. MCCALLEN: Thank you, Your Honor. I think it

1 might make sense for me to go first as the other Acthar
2 private -- private Acthar plaintiff here and then maybe Mr.
3 Harris can respond to both of us if that works for you, Your
4 Honor.

5 THE COURT: That's fine.

6 MR. MCCALLEN: So I guess with regard to the
7 statements that Mr. Haviland just made, you know, from my
8 perspective, Your Honor, we might get some day to the
9 question of whether or not leave to amend should be granted.
10 That is leave to amend the pleadings, but I don't think we're
11 there yet.

12 You know, I think, Your Honor, a little bit of a
13 history here might put some context and be helpful at least
14 with respect to my clients. You know, when we filed our
15 claims in this bankruptcy proceeding we did so without the
16 benefit of any discovery in this case or in the prepetition
17 litigation.

18 Humana, which is one of my clients, filed its
19 lawsuit in 2019 and it had no significant discovery in that
20 case at the time that the bankruptcy cases were filed. I
21 think that, in fact, Humana's motion to dismiss was decided
22 in Mallinckrodt. It just answered, literally, a couple weeks
23 before the bankruptcy petition in this case.

24 It was really part of these cases that information
25 that Mr. Welsh testified to at his deposition, in which I

1 think you will hear about today, started to come to light.
2 You know, as Your Honor recalls, on the same day, April 30th,
3 we filed a motion to estimate. The debtors filed this claims
4 objection; what they style the unsubstantiated claims
5 objection. Your Honor, I am going to have a lot to say about
6 what that means in the context of Allegheny. I think Your
7 Honor is spot on whenever you said Allegheny governs here. I
8 think they're way out side of it in terms of the second and
9 third prongs of Allegheny.

10 With regard to the first prong of Allegheny, Your
11 Honor, the -- when we filed those cross motions, you know,
12 the debtor said your claims are unsubstantiated. There is --
13 you have cited no evidence against these specific boxes and
14 we basically said at that point everything we know we have
15 either learned about from public filings which was very
16 little, frankly, or we had got pursuant to a very restrictive
17 NDA at the outset of the case.

18 So we said to them, okay, fine, you're putting an
19 issue -- the claims, you know, we served them with discovery.
20 I'm not going to belabor the history there. Your Honor
21 remembers. We were in front of you on a 30(b)(6). My
22 colleague, Mr. Freimuth, was in front of you asking for
23 discovery on our estimation motion. You know, the debtors
24 pushed back and they said, no, we can hear this issue, this
25 unsubstantiated claims objection on just this limited factual

1 record.

2 I believe then and I continue to believe now it
3 was an exercise and artificial line drawn, Your Honor,
4 because you just can't disentangle the issues about corporate
5 structure that they offered Mr. Welsh for and that we deposed
6 him on from questions about did something wrongful happen and
7 if so where it happened.

8 So from our perspective, Your Honor, you know, all
9 of those issues are tied together. We now find ourselves
10 three months into this process and, candidly, exactly where I
11 was afraid we would be when we started this which is we have
12 this factual record which we are prepared to move forward on
13 today and, you know, cross-examine Mr. Welsh. I'm sure the
14 debtors are prepared to move forward and give the direct
15 examination of Mr. Welsh.

16 Candidly, I think, Your Honor, whenever you look
17 at the governing law not only Allegheny, but when we get to
18 the evidence, Your Honor, about the second and third prong of
19 Allegheny as well as the Copperweld and other cases you're
20 clearly going to see today, just even on the limited record
21 that we have put together for Mr. Welsh, that our claims
22 would withstand a motion to dismiss and they withstand, from
23 an evidentiary perspective, whatever it is that the debtors
24 are putting forward with this unsubstantiated claims
25 objection. That is what I won't get into right now. I do

1 want to talk about it later because it's not clear to me
2 exactly what it is.

3 I guess what I am trying to say, Your Honor, is I
4 didn't get a chance to confer with Mr. Haviland on the break,
5 We will, obviously, seek guidance from Your Honor and proceed
6 in a way that Your Honor thinks is effective in light of the
7 way Your Honor is seeing the pleadings thus far, but we are
8 prepared to move forward with the evidence today.

9 I think we are going to do enough today that's
10 going to get Your Honor comfortable that our pleading
11 survives whatever this unsubstantiated claims objection
12 really is.

13 THE COURT: Well here is the problem I have with
14 your client's proofs of claim, Mr. McCallen; they filed them
15 and they include a footnote that says we're filing these out
16 of an abundance of caution because we don't actually know
17 whether we have claims against these debtors and we think
18 discovery in the future will show that we do. That is not
19 how the claims process is supposed to work.

20 What should have happened here is as soon as this
21 case was filed and certainly as soon as the bar date was set
22 back in March -- no, when was it set?

23 MR. HARRIS: The bar date was in February, Your
24 Honor.

25 THE COURT: The bar date was in February. I

1 entered the order in, what, October? November 30th I set the
2 bar date order. The bar date was set for February, so you
3 had 78 days. The way the process is supposed to work in
4 bankruptcy is if you're not sure you have a claim against a
5 debtor then you seek 2004 discovery to find out if you do,
6 but neither one of the groups of Acthar claimants here
7 decided to do that, for whatever reason. Instead, they just
8 filed blanket proofs of claim against every single creditor -
9 - excuse me, every single debtor in the corporate structure
10 not knowing whether they had claims or not.

11 I got a problem with that. I got a huge problem
12 with that. I think its bad faith. I also have a problem
13 with the fact that folks actually filed these proofs of claim
14 under penalty of perjury not knowing whether they had a
15 claim. So those are the issues that I have with this whole
16 process. The proper procedure was not filed. It could have
17 been and you didn't do it.

18 So having read these papers, having looked at the
19 proofs of claim I will tell you exactly where I am on this.
20 My view is all of these claims should be dismissed. If you
21 want to say, well, we want a leave to file a late claim then
22 you can file a late claim and I will decide it then under the
23 Pioneer factors the Supreme Court set forth for excusable
24 neglect because you had the time to do your investigation,
25 you had the time to request 2004 discovery to find out

1 whether you actually had claims against these particular
2 debtors and you chose not to do it.

3 I see that as gamesmanship. I see that as let's
4 put pressure on the debtors by bringing claims against every
5 single debtor in the corporate structure, including the
6 generic side and the specialty side, because that is going to
7 screw up the debtor's plan of reorganization.

8 So that is where I am on all of this. So you are
9 going to have to convince me otherwise today. And I don't
10 need to hear the evidence as to whether or not there is
11 claims against these debtors. I want to know why you didn't
12 seek 2004 discovery, why you didn't seek to amend.

13 Mr. Haviland, I don't think saying you want leave
14 to amend in your response to the motion is sufficient because
15 there are specific requirements for a motion to amend that I
16 have to make rulings on and it's not in the papers.

17 Mr. Harris, what is your position? Go ahead.

18 MR. HARRIS: Thank you, Your Honor. That is
19 exactly our view of things. With your helpful guidance that
20 the issue before the court is what we said it was which is
21 whether the proofs of claim, as written, substantiate claims
22 against the non-debtor defendants and there is not a need for
23 an evidentiary hearing for that. I don't know if the
24 claimants are implicitly conceding as they seem to be that as
25 written they do not substantiate a claim. If so we could

1 probably just go forward to a ruling on dismissing them.

2 If they do still dispute that then I would suggest
3 we have oral argument on whether the claims, as written,
4 substantiate a claim. I think it will be abundantly clear,
5 maybe not, that that's the issue of the parties. No one has
6 moved to amend and so that is not before the court.

7 If and when they file we will respond, but our
8 view is we will be able to defeat that. It is extremely
9 prejudicial for them to have laid in wait and to raise a new
10 amended proof of claim later so close to confirmation, but
11 that is not an issue Your Honor has to decide today. As you
12 said today all that is before you is those proofs of claim as
13 written and we are happy to argue that if they are still
14 disputing that they are sufficient on their face. If not,
15 you know, the court understands the issues.

16 THE COURT: Mr. Haviland, you raised your hand.

17 MR. HAVILAND: Your Honor, I'd just like some
18 guidance in terms of whether we should file a formal motion
19 on the heels of the May 21st request. I have been practicing
20 in the Federal District Courts for 31 years and when there is
21 a motion filed, motion to dismiss under Rule 12, which is
22 what I deem the objections to (b), they cite Twombly and
23 Iqbal even though I agree the Allegheny standard applies and
24 is not the same level of pleading (indiscernible). That is
25 how I read the cases.

1 I didn't think that we needed a formal motion when
2 we moved to dismiss with the alternative request leave to
3 amend. The debtors responded in their reply, a week ago, to
4 say leave should not be granted. I would just like to know,
5 if the court is inclined to tell us today, should we file a
6 formal motion.

7 I don't agree with Mr. Harris that we have
8 conceded that the proofs of claim that we filed in some
9 thirty branded debtor cases, Judge, and we tried to be very
10 careful and judicious about the claims we filed and we did
11 not file on all sixty-four cases. I think the court will see
12 that. We did not file, at least to my knowledge, any claim
13 against any generic company that is clearly a generic; SpecGx
14 being the obvious one.

15 We did file as to entities that were at a time
16 part of the brand business, Mallinckrodt LLC for instance,
17 Mr. Hillmer signed contracts. So we tried to be very careful
18 and deliberate about claiming on the brand side business
19 because our view, Your Honor, is when Questcor and
20 Mallinckrodt merged in August of 2014, and it was not an
21 acquisition, it was a merger 50.5 percent of the shares went
22 to Mallinckrodt shareholders, 49.5 went to Questcor; two
23 companies became one. Later this ARD subsidiary was stripped
24 of its assets and found to be insolvent internally back in
25 2018. The rest is just the maneuvers of the corporation with

1 respect to its subsidiary. We think they are just divisions.

2 To me, Your Honor, that is just a question of
3 facts that can be decided on the papers. Mr. Welsh certainly
4 has a lot of knowledge about the reasons why those things
5 were done for tax purposes, but doesn't have a lot of
6 knowledge about the functional aspects of it which is why we
7 asked for the witnesses we did.

8 So I am speaking at length here to find guidance
9 as to whether or not a formal motion at this point should be
10 filed today in which case we will do it so that the issue can
11 be brought to the floor and the court can rule on timing,
12 substance, any issue that goes into what was done back on
13 February 16th, what was done in the context of the April 30th
14 objection and the May 21st response.

15 It seems to me that the parties are coalescing
16 around an approach that the documents are the documents.
17 That is why I made the suggestion, and I'm glad we're
18 discussing it, because we can probably short change the
19 hearing at length by not having to ask Mr. Welsh a number of
20 things he doesn't know about documents he hasn't seen. Then
21 the court can rule on the papers in terms of the proffer.

22 Given where we are I can't leave the fact that
23 we've made a request for leave to amend two months ago and if
24 it's a formal motion that's required, even though there's
25 been a response, then we will file that so that the court can

1 clearly see that that is set for a hearing date and we can
2 decide that because we will certainly put more information in
3 the motion to give the court context based on discussion
4 about the timing and all the material we received in the wake
5 of the court's ruling on a motion to compel.

6 THE COURT: Mr. McCallen, do you have a response?

7 (No verbal response)

8 THE COURT: You're muted, Mr. McCallen.

9 MR. MCCALLEN: Sorry about that, Your Honor. I do
10 have a couple points. Your Honor, thank you for the guidance
11 at the outset of the hearing. I do always think it's
12 instructive and helpful to understand where the court is
13 viewing issues at an early stage of the case.

14 I do want to make a couple points because having
15 heard what Your Honor said I want to let you know why we are
16 where we are from our perspective so you understand. I hope
17 that we are here in good faith.

18 The -- this goes to the point that we, sort of,
19 laid in wait to see what would happen. Your Honor, we tried
20 extensively during these cases and on many occasions to get
21 information from the debtors informally. That did not -- we
22 do not always get what we wanted when we wanted it. In fact,
23 we did not get the level of information we thought we needed.
24 We also -- as you know, the UCC was pursuing a Rule 2004
25 request. We joined in that request and, you know, in

1 retrospect, Your Honor, in light of what Your Honor has said
2 today perhaps we should have been more aggressive in bringing
3 to the court what we felt was informational stonewalling by
4 the debtors.

5 Having heard what Your Honor said today I think
6 that that is something we would have done if we would have
7 known then the way Your Honor was going to view this issue
8 now. You know, the reality is that we largely learned about
9 these entities upon the filing of bankruptcy cases. Your
10 Honor, we really learned, for the first time, that, from my
11 perspective at least, on April 30th whenever the debtors
12 filed this objection that, really, this kind of box by box
13 level scrutiny was going to be a basis to attack our claims.

14 Your Honor has to recall, and this is in Mr.
15 Welsh's first day declaration he talks about this, the reason
16 that the company filed for bankruptcy they had an opioid
17 settlement on the generic side of the business and then they
18 had certain liabilities, Acthar related liabilities coming on
19 the brand side. It was that that led them to file the
20 specialty brand side of the business; not just PLC and ARD,
21 they filed the entire specialty brand side of the business.

22 So from our perspective, you know, Your Honor, we
23 -- in pursuing these claims we thought, you know, I think at
24 the filing of the bankruptcy the expectation among people on
25 our side of the case was ARD and PLC, you know, these are the

1 main entities and maybe some of these other ones are, sort
2 of, related, but that is sort of where the conduct took
3 place, but, in fact, it turned out, Your Honor, that ARD and
4 PLC are a very small part of the story and other entities are
5 a larger part of the story.

6 So, you know, that is just background, Your Honor,
7 that I wanted to try to put that on the record to address
8 Your Honor's comments about how we got here and, you know,
9 the procedure around what we did and whether we brought our
10 plans in good faith.

11 In terms of next steps, Your Honor, I actually
12 think it might -- I know the last thing we want to do is
13 start with another break, but if we're going to do anything
14 other than proceed the way that I think we all envision,
15 which is opening statements, short opening statements
16 followed by Mr. Welsh and cross, followed by closings, I
17 would like the opportunity to confer with my colleagues. I
18 think there has been a lot of information here that has been
19 conveyed from the court to the parties. I think I would like
20 an opportunity to absorb that and discuss it with my clients
21 if that is possible.

22 THE COURT: Alright, let me hear from Mr. Harris
23 first.

24 MR. HARRIS: Thank you, Your Honor. Again, our
25 view is there is not a need for an evidentiary hearing at

1 this point. The issue is what do the proofs of claim say and
2 assuming the facts are true did they substantiate a claim
3 against each debtor against whom it was filed. That can be
4 determined on the basis of pleadings, the proofs of claim,
5 and the law which is in the briefs. We're happy to go to
6 oral argument on that.

7 In terms of a few points that were made the ad hoc
8 group did not move (indiscernible). What they said in a
9 motion to dismiss is that in the future they would seek leave
10 to amend at some unspecified point when unspecified discovery
11 is completed and I don't even know what that amendment would
12 be because they didn't file an amended proof of claim. So
13 the thought that they had actually moved to amend in some
14 unspecified way at some unspecified time is just not
15 accurate.

16 In terms of Humana they have not sought leave to
17 amend and Attestor. I actually received hundreds of
18 thousands of documents prepetition. They received millions
19 of documents in the bankruptcy. They saw pleadings in the
20 bankruptcy filing case in the early stages that indicated the
21 ownership of IP, the licensing structure, many things, all of
22 which would put them on notice as to what entities are
23 involved. It had gotten the entire Acthar production, the
24 prepetition lawsuit, which is millions of pages and they have
25 all the facts currently about Acthar entities do what. In

1 fact, they stipulated with us that they would rely on the
2 facts in their reply brief in exchange for us not pursuing
3 further discovery from them. And despite that they chose not
4 to amend.

5 The idea that you just heard that somehow
6 respecting corporate formalities and limiting each corporate
7 entities liabilities to its own liabilities was a surprise to
8 them. They view that that was somehow surprising to them is
9 incredible. That is the foundation of corporate law. It is
10 the foundation of how Chapter 11's are run. The thought that
11 this did not occur to them until they saw our omnibus
12 objection that they would have to substantiate a claim
13 against each entity is just not credible.

14 So at this point we would propose that we go to
15 oral arguments on whether the proofs of claim as written
16 substantiate unless the court views that it does not need the
17 argument because the paper are sufficient.

18 THE COURT: Thank you, Mr. Harris.

19 Mr. Haviland?

20 MR. HAVILAND: Judge, one final point and it's
21 what I started with. We do have a substantial record that we
22 supplied to the court and the parties and that is now before
23 the court. I can't let Mr. Harris's comment about some
24 stipulation to rely upon what was in the papers go
25 unanswered. We did not -- we, the ad hoc Acthar group, did

1 not make that agreement. I know counsel is aware of that.

2 They had asked in exchange for agreeing not to
3 take our client's depositions, which I pointed out to the
4 court, (indiscernible) was deposed just the other day. We
5 put our clients up. And so we did not make any agreement
6 that we would rely upon simply the response papers because
7 there is more to it than that. And whether the court is
8 going to go forward with an evidentiary hearing or some other
9 vehicle to get these issues properly framed and before the
10 court we're not resting on our opposition to the objections
11 without making that substantial proffer of those exhibits.

12 THE COURT: Mr. McCallen, in your papers you
13 actually state flat out that you were going to -- after
14 discovery was completed you were going to make a
15 determination and work with the debtors to see whether you
16 could dismiss the claims against the generic brand debtors.
17 Have you made that determination?

18 MR. MCCALLEN: I think what our -- we have not
19 yet, Your Honor. The short answer is we have not. To the
20 point that Mr. Murtagh was making earlier there has been no
21 further discovery on this motion after the deposition of Mr.
22 Welsh.

23 We have documents from the debtors that represent
24 which those entities are and we would, you know, like the
25 opportunity, as we anticipated doing during discovery, is

1 taking further discovery, confirming the fact that the
2 generic side is the generic side, the debtors -- the
3 specialty brand side is the specialty brand side. Then we're
4 going to dismiss those generic claims.

5 We have no -- we have been very clear about that.
6 The debtors have also, you know, not reached out to us to
7 say, well, let's talk about how we can do this. So, Your
8 Honor, we haven't had that conversation with them. I do
9 think we would want some more confirmatory discovery, but it
10 is our intention to do that, Your Honor.

11 THE COURT: You see that's another problem because
12 you have had months do that and I don't understand why you
13 haven't. The only reason I could think of as to why you
14 wouldn't is for hold up factor because you're holding up the
15 debtor's proposed plan of reorganization by maintaining
16 claims against the generic side without any basis for knowing
17 whether you -- you've had months to take discovery on that
18 issue. I am just really frustrated with where this process
19 stands.

20 Mr. McCallen, I am going to give you the
21 opportunity to take a break. I am not going to hear any
22 evidence today. I don't think I need to. I will hear brief
23 arguments as to why, as written, these proofs of claims
24 should not be dismissed or whether or not I should grant
25 leave or grant leave to seek leave to amend because I'm not

1 going to grant leave to amend based on the record I have
2 before me. We will take it from there. That is what I want
3 to hear about when we come back.

4 So let's take -- let's recess until -- how much
5 time do you think you will need, Mr. McCallen?

6 MR. MCCALLEN: Ten minutes should be fine, Your
7 Honor.

8 THE COURT: Alright, well let's take a little bit
9 longer. Let's recess until eleven o'clock.

10 MR. MCCALLEN: Thank you, Your Honor.

11 (Recess taken at 10:35 a.m.)

12 (Proceedings resumed at 11:05 a.m.)

13 THE COURT: Alright, we are back in the record.
14 Mr. McCallen, did you have an opportunity to discuss the
15 issues and do you have anything to add?

16 MR. MCCALLEN: No, Your Honor. I think in light
17 of the court's guidance we would proceed directly to
18 argument. I don't think there's anything further that we
19 need to discuss at this point.

20 THE COURT: Alright, so the argument that I want
21 to hear is do these proofs of claim, as drafted, allege facts
22 sufficient to establish a claim against the debtors against
23 whom those proofs of claim were filed. If they do not is the
24 proper way to proceed to dismiss those claims or is it to
25 grant leave to amend those claims?

1 So with that, Mr. Harris, you raised your hand.

2 MR. HARRIS: Thank you, Your Honor. I will
3 address those two points in order. I will first talk about
4 why each challenged claim should be disallowed under the
5 first step of Allegheny and then I will talk about why that
6 disallowance should be with prejudice given where we are in
7 the case today.

8 So I don't believe this first question is
9 difficult. Under Allegheny which governs here, no one
10 disputes that, before there is a *prima facie* valid proof of
11 claim, so in order to assert a *prima facie* valid proof of
12 claim the claimants have to satisfy the first step of
13 Allegheny which is,

14 "The claimant must allege facts sufficient to
15 support the claim."

16 That is the standard and that also means that the
17 factual allegations in the proof of claim there must be
18 allegations of specific wrongful conduct attributable to the
19 debtor in question and we cited several cases applying that
20 standard to disallow claims. It was the In Re Tribune case,
21 the Hilton v. Hongisto case as examples.

22 So just attaching a prepetition complaint to a
23 proof of claim, if the complaint doesn't allege any facts
24 about that debtor does not satisfy the standard. There is no
25 magic to the words of calling something a complaint. The

1 complaint actually has to say something about the debtor
2 against whom the claim is filed.

3 The main case that the claimants rely on, F-
4 Squared just confirms that. I am going to quote it,

5 "Multiple courts and commentators also require
6 that a proof of claim allege facts sufficient to support the
7 claim. A reviewing court will assume the allegations are
8 true and ask whether the facts established are the necessary
9 elements of a claim."

10 That's F-Squared, that is what Allegheny says. So
11 you look at what are the facts alleged in the proof of claim.

12 Here, the challenge proofs of claim, including all
13 the facts in the complaints appended thereto, fail that
14 threshold. So the issue isn't assertion of facts. It's not
15 about whether they documented or proved those facts. For
16 today we're assuming they have.

17 So here is where we are, there are zero facts
18 asserted against each of the non-defendant debtors, no facts
19 at all. I heard -- I saw in the briefs two responses to
20 that. One is that there is a small set of proof of claims,
21 in particular those that were filed by United Healthcare and
22 Optum RX, claims that Attestor has now bought, that define
23 Mallinckrodt to include every debtor, but that is just
24 impermissible group pleading. It doesn't satisfy the
25 obligation to allege facts about the specific against whom

1 the claim was filed.

2 We cited several cases to that effect in our brief
3 including In Re Frohoff [phonetic], In Re Conex Holdings, and
4 In Re PennySaver. Notably, the claimants don't cite any case
5 saying that it's sufficient to make a group pleading against
6 60 defendants together because there are no such cases. It
7 also violates the requirement that a proof of claim must
8 clearly identify the debtor and make a demand specifically
9 against that debtor. That is the (indiscernible) case we
10 cite.

11 So clearly those couple of proofs of claim that
12 just lump 60 debtors together and make statements about
13 Mallinckrodt's generics they are not sufficient. The only
14 other defense to the wording of these proof of claims that
15 any claimant makes is that their proof of claims refer
16 "unnamed" co-conspirators. That is insufficient for at least
17 three reasons.

18 First, the reference to an unnamed co-conspirator
19 is not a reference to the non-defendant debtors and that is
20 because a corporation can't conspire with its own affiliates.
21 Copperweld, the case that Humana and Attestor rely on and
22 that you heard the ad hoc group mention as well, confirms
23 that. You cannot conspire with your affiliates.

24 Second problem with this argument is that even
25 this -- even if this was supposed to be a reference, the

1 unnamed co-conspirators were supposed to be a reference to
2 the non-defendant debtors the failure to actually name them
3 is a failure to properly identify them and, thus, violates
4 the requirements that a specific debtor be individually
5 identified. We cited the Springer case to that effect and we
6 cited others as well; Smith v. Department of Corrections New
7 Jersey, and In Re PennySaver.

8 The third problem with this argument about the
9 reference to unnamed co-conspirators is that even if the
10 proofs of claim had actually said that the particular debtor
11 was a co-conspirator that would still not be nearly enough
12 because all that is, is a legal conclusion. That is not a
13 factual allegation.

14 We cited several cases holding that, for example,
15 Bell Atlantic v. Twombly, "A bare assertion of conspiracy
16 will not suffice." (Indiscernible), Third Circuit case. It
17 is, "Not enough for a complaint to simply make conclusory
18 allegations of concerted action, but be devoid of facts
19 actually reflected in a joint action."

20 The In Re (indiscernible) Group antitrust
21 litigation which hold that an antitrust complaint "Fails to
22 adequately plead the existence of a conspiracy where
23 plaintiffs never state that any or all of the defendants have
24 joined the actual conspiracy. That case also noted that in
25 the City of Rockford case against ARD, so the actual case the

1 ad hoc group brought pre-conspiracy,

2 "Plaintiffs conspiracy claim was dismissed for
3 conclusory pleading against an unidentified co-conspirator
4 where the complaint contained scant mentions of the co-
5 conspirator in its role as a part of the dealing
6 arrangement."

7 So it is Black Letter Law that just saying someone
8 is a co-conspirator is insufficient. So that is not a
9 defense to these proofs of claim either. So because the
10 private Acthar plaintiffs did not meet their initial burden
11 under the first step of Allegheny their proofs of claim never
12 achieved validity, you never get to the second or third steps
13 of Allegheny and the claims should be disallowed.

14 I do want to, just to confirm that, make some
15 general points of law that support this. These are all in
16 our brief.

17 First, the fact that the non-debtor defendants are
18 affiliates of ARD and PLC does not create liability in any
19 way. That is Black Letter corporate and bankruptcy law. We
20 cited several cases for that. In Re HH Liquidation, that's a
21 Bankruptcy District of Delaware, it is axiomatic that parents
22 and subsidiary corporations are separate entities having
23 separate assets and liabilities; hence, the parent's
24 creditors have no claim for the subsidiaries assets and vice
25 versa. We also cited In Re Regency Holdings, Southern

1 District of New York bankruptcy case,

2 "A part seeking to overcome the presumption of
3 separateness must pierce the corporate veil or prove the two
4 entities should be substantively consolidated."

5 So a corporate entity is liable only for its own
6 debts and its own (indiscernible). To the extent that the
7 claimants here are trying to articulate theories of alter-ego
8 or veil piercing those are estate claims, they cannot be a
9 part of the proof of claim of an individual creditor against
10 an estate. We cited several cases to that effect; Emerald,
11 In Re Buildings by Jami [phonetic], In Re Tronics. So the
12 fact that they are affiliates is not enough.

13 Specific to the actual claims that they have
14 raised that is true as well. If you look at antitrust law,
15 and we cited several cases to this effect, you know, Attestor
16 and Humana seem to be relying on a theory that asserting
17 claims against one member of the corporate enterprise is
18 sufficient to establish antitrust claims against the rest of
19 the corporate enterprise. That is completely wrong. It is a
20 deep mischaracterization of the cases that Attestor actually
21 cites which instead votes the plaintiffs are required to show
22 that each defendant independently participated in an
23 enterprise scheme.

24 So if you look at the main case they rely on,
25 Copperweld, it actually rejects intercorporate liability

1 under Section 1 of the Sherman Act,

2 "If a parent and a wholly-owned subsidiary do
3 agree on a course of action there is no sudden joining of
4 economic resources that it previously served different
5 interests."

6 Courts can uniformly reject it, Attestor's
7 argument, that under Copperweld the plaintiff does not need
8 to allege the anti-competitive actions of each separate
9 corporate defendant. We cited several cases to that effect;
10 there's the In Re Insurance Brokerage Antitrust Litigation
11 Third Circuit case,

12 "Contrary to plaintiff's suggestion it does not
13 follow through Copperweld that subsidiary entities are
14 automatically liable under Section 1 for any agreements which
15 the parent is the party."

16 We also cited (indiscernible), Tenth Circuit case
17 where the plaintiff sought to extend Copperweld to hold
18 parent and sibling entities as one reliability even when
19 there is no evidence that each were involved in the challenge
20 conduct. The court rejected this. So it is the law in the
21 antitrust liability. It is that the plaintiff must allege
22 facts that each defendant independently participated in any
23 alleged antitrust scheme.

24 We cited the Lennox case for that. All these are
25 cases that Humana cite. The Lennox case said that Lennox was

1 still required to come forward with evidence that each
2 defendant independently participated in the enterprise scheme
3 to justify holding that defendant liable as part of the
4 enterprise. Arandell, the Ninth Circuit case,

5 "Copperweld does not support holding a subsidiary
6 liable for the parent's independent conduct."

7 That is with any antitrust defendant plaintiffs
8 must report evidence that CES, a particular defendant,
9 engaged in competitive conduct. Or the Insurance Brokerage
10 Antitrust case Third Circuit again where,

11 "Defendants are not plausibly alleged to have,
12 themselves, entered into unlawful agreements. The antitrust
13 claims against these entities must fail."

14 So that is the law. They have to allege facts
15 that each defendant engaged in anti-competitive conduct.
16 These proofs of claim allege nothing about the anti-
17 competitive conduct of each of the debtors that they are
18 filed against. And it's not surprising because of that
19 because there are only two types of anti-competitive conduct
20 alleged; the 2013 acquisition of Synacthen and the exclusive
21 distributorship arrangement with (indiscernible). There is
22 no allegation in the proofs of claim that any of the non-
23 defendant debtors engaged in either of those activities. In
24 fact, both of those activities started before Mallinckrodt
25 even acquired Acthar, acquired Questcor. So it's not

1 surprising that there are no allegations that other
2 Mallinckrodt entities were involved in these.

3 Antitrust liability, the same thing is true for
4 RICO liability. The cases are clear you have to allege that
5 each defendant, each debtor independently engaged in a
6 racketeering activity either by conducting it or directing
7 it. That is the reason the (indiscernible) case, the Supreme
8 Court case 1993,

9 "It is clear that Congress did not intend to
10 extent RICO liability under 1962(c) beyond those who
11 participate in the operation or management of an enterprise
12 for pattern of racketeering activity."

13 So the cases are very clear that just associating
14 or doing business with a related entity is insufficient to
15 create RICO liability. That is the In Re Insurance Broker
16 Antitrust case again,

17 "Mere association with an enterprise does not
18 violate 1962(c)."

19 Likewise, we cited cases saying merely providing
20 goods and services that benefit the alleged RICO enterprise
21 is not liability. That is University of Maryland v. Peat
22 Marwick case, Third Circuit, and the James Streibich
23 Revocable Trust case. Likewise, we cited cases saying merely
24 receiving revenues that are derived from a RICO scheme is
25 also not enough for RICO liability. That is the James

1 Streibich Revocable Trust case again where it granted a
2 motion to dismiss where the plaintiff provided "nothing to
3 suggest that wholly-owned corporate defendants were anything
4 more than pass-through vehicles for funding."

5 Likewise, we cited the Lerner v. Colman case which
6 found that an alleged rule consisting of "passive reception
7 of fraudulently acquired stock and promissory notes did not
8 constitute RICO liability." We also cited cases that just
9 providing a license that someone else uses in racketeering
10 activity is not enough. That is the Goran case. Then we
11 cited cases that provided financing is not enough, that is
12 the (indiscernible) case, "Passive financing arrangements are
13 insufficient to give rise to liability."

14 And the same thing is true for unjust enrichment.
15 I make just two points about that. First off is the extent
16 that there is any unjust enrichment claim that is cognizable
17 in the proofs of claim, it is a disguised alter-ego veil
18 piercing claim that somehow value has flowed up to, I guess,
19 all debtors somehow and, therefore, the claimant should be
20 able to access that value wherever it went. That is just a
21 disguised veil piercing claim attempting to disregard
22 corporate formalities.

23 We cited several cases saying that unjust
24 enrichment cannot be used to nullify corporate separateness
25 without satisfying the elements of alter-ego and veil

1 piercing. That includes the QVC case which is a Third
2 Circuit 2016 case. We also cited In Re Citizens and Bank of
3 New York Mellon. And because they are really just alter-ego
4 and veil piercing claims claimants cannot put them in their
5 proof of claim. They are not a valid claim against these
6 entities.

7 The second problem with these is that even if they
8 had standing to bring them an unjust enrichment claim also
9 requires conduct by the actual debtor. Even if it doesn't
10 require wrongful conduct it does require that the defendant,
11 itself, engaged in conduct and that that conduct had a direct
12 relationship with the plaintiff's loss. We cited the Shubert
13 (indiscernible) case, New York Superior Court 2020,

14 "There must be a causal connection between the
15 plaintiff's claimed loss and defendant's actions."

16 We also cited Betty v. BMW, (indiscernible), and
17 the Kagan [phonetic] case. So unjust enrichment as well
18 requires an allegation of conduct by the defendant and that
19 that conduct directly caused the plaintiff's loss. Here
20 there are no facts alleged as to any conduct by the non-
21 defendant debtors.

22 So where does that leave us? Clearly on their
23 face these claims do not substantiate a claim against the
24 non-defendant debtors. They should be disallowed. So the
25 real issue is whether that disallowance should be with

1 prejudice. We argue it should because there is no excusable
2 neglect here for the failure to properly file proofs of claim
3 or, at least, amend them by now. It would be highly
4 prejudicial to allow an amendment now so close to
5 confirmation, so disruptive to do that now.

6 So the courts apply an equitable test focusing on
7 prejudice, delay and bad faith to determine whether to permit
8 a proposed amendment after the bar date. So we cited In Re
9 Exide and In Re Brown. Prejudice is the most heavily
10 weighted factor of this. Here there is no excusable neglect
11 for failure to have filed a proof of claim or, at least,
12 amended them by now. They certainly would be highly
13 prejudicial.

14 Let me just review the facts for the court. Prior
15 to the bar date both sets of claimants were aware of, at
16 least the material facts in the case that other -- that other
17 entities had some role if they wanted to substantiate those
18 claims.

19 In terms of the Acthar claimants they were given
20 over one million documents in prepetition discovery, fifteen
21 depositions including many documents that described the role
22 of other Mallinckrodt entities. They had documents and we
23 attached those documents to our brief including slides that
24 showed that MPIL was the contracting entity for Acthar
25 management, that other entities owed the IP and engaged

1 licensing agreements. We showed there were attached
2 documents indicating that MPIL approved the strategic plan,
3 documents indicating that MPIL was involved in setting the
4 price for Acthar. Humana received several of those documents
5 as well prepetition.

6 In addition, there were bankruptcy filings in this
7 case before the bar date. The IP restructuring motion, which
8 is Docket No. 385, was filed in November 2020 showed the
9 Acthar ownership and licensing structure as of the bar date;
10 in particular that Mallinckrodt ARD owed the Acthar related
11 IP, that it licensed it to Lux IP S.a.r.l., sub-licensed it
12 to MPIL which then owed Lux IP S.a.r.l. licensing fees.
13 Those are the facts that I imagine they would try and amend.
14 Those are the key facts they were aware of the bar date
15 whether they paid attention to it or not.

16 Then after the bar date, but well before this
17 hearing, we provided extensive discovery to both sets of
18 claimants. Millions of pages of documents, all the data that
19 is needed to establish the Acthar related conduct of each of
20 the non-defendant debtors and they chose not to amend. So
21 there is not excusable neglect for failing to file a proper
22 proof of claim or, at least, amending it before this hearing.

23 It would also be highly prejudicial to allow that
24 amendment now. It would be a hugely wasteful and inefficient
25 use of the party's resources and the court's resources. We

1 have a hearing today. This motion was filed three months
2 ago. We have already extended the hearing date twice to
3 allow them to conduct discovery and incorporate those facts
4 wherever they chose to be. It would be hugely wasteful to
5 the estate and the court to repeat this whole process later.

6 It would also be extremely prejudicial to allow
7 the claimants to amend later, to string out the claims filing
8 process after the bar date and after this hearing. I'm sure
9 Your Honor remembers we brought this objection in April and
10 we're very clear about why we did this. We did this in order
11 to provide clarity to the estate and the court in advance of
12 confirmations so we would know whether there were surviving
13 claims against other boxes and if so whether we had to
14 conduct an estimation hearing on those surviving claims
15 against other boxes.

16 If you recall, Humana told you that if we do have
17 to go that route it would be extremely lengthy and timely.
18 They estimate it will take four months for discovery and at
19 the end of trial. We tried to avoid all this by fronting
20 these issues and filing this estimation motion. It would be
21 highly prejudicial for them now, months later, to file a
22 motion to amend which, itself, will take a month to deal
23 with. And if they're permitted to amend then we have a
24 hearing on the legal sufficiency of those amended claims
25 under Allegheny step one. And if any are legally sufficient

1 then we have to go through an estimation process at that
2 point possibly.

3 They told repeatedly that they knew that we are
4 somehow the bottleneck, that we have not been providing
5 discovery. They have the discovery. They are the ones who
6 are now slowing down this process and keeping these claims
7 open apparently for leverage purposes. They should have
8 started whenever they needed back at the beginning of the
9 bankruptcy process.

10 They should have come to court if they were
11 unhappy with the discovery that they had gotten. We
12 repeatedly invited them to do so. They had gotten the
13 discovery that they need. They did not amend the claims. It
14 is way too late and would be highly prejudicial to not just
15 the debtors, but to this entire bankruptcy process for them
16 to amend in the future. So we believe that disallowance of
17 these claims should be with prejudice.

18 With that I will pause, unless the court
19 questions, to allow my colleagues to speak.

20 THE COURT: Well, Mr. Harris, if I dismiss the
21 claims, does that give, is it because of the fact that they
22 failed to allege facts sufficient to show that there's a
23 claim against these debtors, is there anything that stops
24 them from then filing a motion to file a late-filed claim?

25 MR. HARRIS: Obviously, anyone can file a motion.

1 If it disallowances with prejudice, they would have to
2 satisfy the standard for that. I don't think even if they
3 file a motion for a late-filed claim, they would be able to
4 satisfy it for the reasons I just described. I think the
5 same standards would apply, which is was there excusable
6 neglect, and is there prejudice to the debtors for the late
7 filing. So, I think that issue can be decided now in the
8 context of determining to disallow these claims with
9 prejudice.

10 But, of course, they could file a motion if they
11 choose to.

12 THE COURT: Okay. Thank you, Mr. Harris.

13 Mr. McCallen, I'll let you go first and then I'll
14 go for Mr. Haviland.

15 MR. MCCALLEN: Okay. Thank you, Your Honor.

16 Mr. Harris made a lot of points and I'm going to
17 try to hit them, or most of them, as many as I could make
18 note of, and I'll try to do efficiently, Your Honor.

19 Your Honor, I think Mr. Harris acknowledges in his
20 presentation that really the standard on this motion is that
21 of notice of pleading. The case law is clear that it's not
22 even a 12(b)(6) type standard, but under for a bankruptcy
23 proof of claim, there's actually even a lower threshold.

24 I don't think they can -- and I don't think they
25 do argue that they're not on notice of the relevant conduct,

1 because we have a 50-page pre-petition complaint, at least on
2 behalf of Humana, we do, and that's survived two motions to
3 dismiss in terms of, does it allege valid claims under the
4 antitrust RICO and unjust enrichment and other state laws.

5 It's really a group-leading argument and Mr.
6 Harris alluded to this. So, it's not so much is there
7 sufficient allegations of conduct, but do you have
8 allegations against the boxes for conduct in each of those
9 boxes.

10 And when it comes to that issue, Your Honor, I
11 think, obviously, the complaint that we've attached to our
12 proofs of claim, it was filed pre-petition, it was before we
13 knew what we know now, so there was just literally impossible
14 for those documents to contain the allegations of the facts
15 that are put in our objection.

16 But, again, when you come back to the idea of
17 notice, there's really no argument the debtors can make from
18 a pleading perspective, hey, we don't have notice of what you
19 guys think happened. All of the facts that we have were
20 obtained from them via discovery.

21 They know the corporate structure. They know the
22 divisions, and that gives them argument. Then they made them
23 in their pleading, you know, they made evidentiary arguments
24 and they made other arguments about what that means, and we
25 didn't get to those today, but from a first step of Allegheny

1 or even, frankly, a 12(b)(6) standard, and I think the debtor
2 unfairly mix them up at times, but under either circumstance,
3 the purpose of that is to give the defendant, or here the
4 debtors, fair notice of the allegations.

5 And I think when it comes to that, they might have
6 arguments down the road that we can't prove-up those claims,
7 and, again, then maybe there's certain boxes those claims
8 shouldn't be against, but in terms of a notice standard, I
9 don't think they can really make that claim.

10 And they cited, Mr. Harris cited the F-Squared
11 case, that's F-Squared Investment Management; that's a case
12 from this Court. And what the Court said there, I think is
13 important. The Court said that it's a relatively low
14 threshold that is less burdensome in the federal, civil
15 pleading standard, when talking about standard under proofs
16 of claim, and, again, re-emphasized the fact that as long as
17 a proof of claim provides fair notice and the Court can glean
18 an actionable claim from the complaint, then it should
19 entertain the parties' case.

20 THE COURT: Well, if the actionable claim in the
21 complaint is against debtors A and B, how does that give
22 notice to debtors C, D, E, F, G, H, I, J, K that there's a
23 claim against them? How does it give the Court the
24 opportunity to know that there are claims against those other
25 debtors?

1 MR. MCCALLEN: So, Your Honor, I think, and this
2 comes back -- this goes to the other point that I think Mr.
3 Harris was speaking to, which is that the case law
4 construing, particularly on the antitrust side, claims
5 against multiple entities within a single enterprise, and
6 this was the Copperweld case which he alluded to, and then
7 the progeny, I think various circuit courts have now
8 interpreted Copperweld.

9 THE COURT: Well, then, why didn't Humana, pre-
10 petition, sue all of them? If it's that easy, if it's easy
11 to say if you're in the corporate structure, we can sue you
12 for antitrust liability, why didn't you sue them pre-
13 petition?

14 MR. MCCALLEN: Well, two things, Your Honor.
15 First, we didn't know about them.

16 THE COURT: Well, it's a publicly traded company.
17 You could certainly look at their SEC filings and know who
18 was in the corporate structure.

19 MR. MCCALLEN: In this situation, Your Honor, the
20 level of detail we have here and the additional entities, we
21 did not know that. And, actually, Your Honor, I respectfully
22 disagree, the information we presented to the Court, via our
23 objection, that we obtained through discovery in this case
24 about, you know, the division between holding the IP in a
25 box, that being licensed to different boxes, which are the

1 ones who make the decisions about marketing, sales,
2 distribution, and, then, you know, funneling that down to ARD
3 and various other facts that we talked about in our
4 objection, that was not public information.

5 THE COURT: Well, here's the --

6 MR. MCCALLEN: And I don't think the debtors ever
7 claimed that it was.

8 THE COURT: Well, here's the problem. It's not
9 included in the proof of claim that's before me. You
10 included it in your objection, but it's not in your proof of
11 claim and you didn't move to amend the proof of claim.

12 MR. MCCALLEN: Understood, Your Honor.

13 And I can address the amendment point now or I can
14 finish out on the pleading argument and then move on to that
15 point.

16 THE COURT: Go ahead. I don't want to interrupt
17 your flow.

18 MR. MCCALLEN: Sure. Thank you, Your Honor.

19 So, coming back, I was talking about Copperweld.
20 So, let's talk about what Copperweld says. In that case, the
21 Court held that a parent and its subsidiary cannot be co-
22 conspirators for purposes of establishing conspiracy under
23 Section 1 of the Sherman Act.

24 I think me and Mr. Harris agree about that. I
25 don't think we disagree about the holding of it. And the

1 Court explained that the reason for this is that the parent
2 and its related subsidiaries share the same corporate
3 consciousness and have a unit of interest, and as a result,
4 the Court said -- and I'll just use one quote -- the Court
5 said:

6 "The coordinated activity of a parent and fully
7 owned subsidiary must be viewed as that of a single
8 enterprise."

9 And what courts that have interpreted Copperweld
10 have said is that the reasoning of Copperweld permit pursuit
11 of antitrust claims, based on the coordinated conduct of
12 multiple entities, functioning as a single enterprise and
13 that in some circumstances, proof about each entity's
14 separate (indiscernible) is not necessarily relevant.

15 And what I want to say, Your Honor, is that Mr.
16 Harris, I believe, mischaracterizes our argument. They say
17 that we miscite these cases, but I think they miscite us,
18 because we're not saying, and we've never said that an entity
19 can be held liable solely by virtue of their corporate
20 affiliation with other debtor entities. That's not our
21 argument. It's never been our argument.

22 And all of the cases, and the pieces of Copperweld
23 and Lennox (phonetic), and Arandell (phonetic) and the other
24 cases that Mr. Harris and his attempted pointed you to in
25 their brief and (indiscernible) argument, that's what they're

1 all saying. They're all making that point, that, hey, just
2 by (indiscernible) of being a sister corporation, that's not
3 enough.

4 And our point is, we're not saying that's all
5 there is. We think at the end of the day there is a set of
6 core entities, and, Your Honor, I think, you know, this is
7 maybe a good time to tell you how I sort of think that the
8 discovery that we've obtained from the debtors and how the
9 corporate structure works, I almost think of it as a set of
10 three concentric circles. You have the inner-most core of
11 entities that we now know about who are integrally involved
12 in the manufacture or the creation of intellectual property
13 through research and development, manufacture, based upon
14 that research and development, then distribution and sale of
15 that product. And that's about 10 or so entities that fit
16 within that core group of entities that are involved in that
17 concept.

18 And then, thereafter, you have another set of
19 entities, what I like to think of as sort of a second
20 concentric circle, which are entities that benefited from
21 that or we believe may have benefited from that, because the
22 discovery from that is still ongoing. The debtors are
23 producing documents to us, no doubt, and we're reviewing them
24 as quickly as we can -- there's been a lot of production --
25 and we are setting depositions to comply with. We haven't

1 had any additional depositions yet. We've set them to comply
2 with the Court's scheduling order for plan confirmation, but
3 we've been planning to take those depositions in early
4 August.

5 But we know that a lot of entities benefited from
6 the proceeds of Acthar, which is, by far, the debtors' most
7 profitable and the largest revenue generator for the debtors.
8 You know, when you actually look at the first day
9 declaration, I think in 2019, the year before the bankruptcy
10 petition, Acthar earned for the debtors something just shy of
11 a billion dollars. And when you look at the entire
12 enterprise, Specialty Brands and Generics, their revenue was
13 about \$3.1 billion. So, Acthar is a third of this business
14 and it's the reason that they've said that they ultimately
15 put this entire Specialty Brands business into bankruptcy.

16 And so, this Acthar revenue, once it got taken in
17 through ARD and distributed up the corporate chain, it was
18 used, we believe, for a variety of corporate purposes. It
19 was used to pay down debt. It was used for purposes
20 unrelated to Acthar, and purposes related to Acthar,
21 distributed throughout that very complicated corporate
22 structure.

23 And, you know, beyond that, Your Honor, I think
24 the third circle of entities are the rest of the Specialty
25 Brands, because like I said, we don't have any intention of

1 going after the Generics entities. It would be the remainder
2 of the Specialty Brands entities.

3 And it may turn out, Your Honor, that the some or
4 all of those Specialty Brands entities, at least with respect
5 to our direct claims, putting aside substantive consolidation
6 for a minute, that some of those should be dismissed. But
7 when I come back to that, Your Honor, that is a level of
8 detail and level of interconnectedness among entities that no
9 SEC filings pre-petition anywhere near to describing. And
10 that's what we've been untangling as part of the discovery
11 process.

12 THE COURT: Well, what you just described to me,
13 Mr. McCallen, the transfer of funds amongst the various
14 debtor entities, that sounds like a fraudulent conveyance
15 claim, which does not belong to you; it belongs to the
16 estate.

17 MR. MCCALLEN: So, let me address, that Your
18 Honor, because that's one of the points that the debtors made
19 and Mr. Harris made in his presentation just now. And I want
20 to say a couple of things.

21 First, we are not pursuing alter-ego claims. They
22 keep trying to say that. And every time we look at any
23 entity, they say that's alter-ego. That's veil-piercing.
24 That's not what we're saying.

25 The same conduct can give rise to multiple

1 different claims at the same time. There could be conduct
2 about moving (indiscernible) that's between the debtor
3 entities that gives rise to veil-piercing or fraudulent
4 transfer claims, true. But that same conduct can also give
5 rise to other causes of action; for instance, an unjust
6 enrichment claim. That's a direct claim we would have
7 against that entity and that's an equitable claim under state
8 law designed to allow parties to get proceeds that were
9 improperly, or without a valid basis, distributed to other
10 entities.

11 Now, what Mr. Harris says in response to that is,
12 but there's got to be some level of culpable conduct at that
13 entity, and I have a couple of responses to that. One, and
14 it's kind of difficult, Your Honor, because we're talking, I
15 think, literally, about dozens of entities, but number one, a
16 lot of those entities, I believe are run by the same
17 individuals that are making decisions about the transfers
18 themselves and are involved in the entity that we would view
19 as concentric circle number one. There's incredible overlap
20 here among decision-making among the debtors.

21 Number two, a lot of the entities that Mr. Harris
22 is going to point out is he's going to say, that's a passive
23 entity. It doesn't do anything. It's just a boxed asset.
24 There's no employees. There's no business operations there.

25 And for that, Your Honor, I would say that is a

1 really problematic position for the debtors to take and if
2 the Court were to ultimately adopt it, because what the
3 debtors have done, and, Your Honor, at some point, we
4 ultimately hear the evidence on, this we'll get into this in
5 much more detail, but I think it's important that Your Honor
6 understand.

7 The two entities that they are saying we can have
8 claims against, ARD and PLC, have very little value relative
9 to the overall value that Acthar provided to the debtors'
10 business. According to their liquidation analysis, they say
11 that most of the value related to Acthar resides in an entity
12 or at least pre-petition it resided in an entity called
13 Mallinckrodt ARD IP, and that's the entity that holds their
14 intellectual property.

15 And intellectual property consists -- it's not a
16 patent-protected drug at this point, so the supposedly
17 valuable intellectual property consists of research and
18 development about potential use for Acthar, how to make
19 Acthar, things like that. That is a passive entity that has
20 no business praising. It has no employees. It does nothing,
21 other than hold the Acthar IP.

22 And the position that the debtors are taking that,
23 hey, you need to have actionable conduct at every entity, if
24 that were true in this situation, not only this debtor, but
25 every debtor. This would be a roadmap for every corporation

1 in America, put your assets in a passive entity that cannot
2 engage in any conduct, because it doesn't have any employees.
3 It doesn't have business operations, other than holding the
4 things that you care most about, and you can't touch it in a
5 litigation.

6 You can't touch it in a bankruptcy, certainly, but
7 you couldn't touch it in a litigation, according to them,
8 either, because if there had been no bankruptcy and we took
9 discovery and did all this in California Federal Court, they
10 would say, we can't (indiscernible) claims against the entity
11 that holds the IP, for instance, because it's just a passive
12 entity and it didn't do anything.

13 THE COURT: Well, two observations, Mr. McCallen.
14 One, you quoted to me the Copperweld case, and the quote you
15 gave me was that you have to show coordinated activity
16 between the entities. So, there has to be some activity,
17 even under Copperweld.

18 Your proofs of claim don't allege any activity by
19 any of these debtors that you've asserted these proofs of
20 claim against, beyond the entity that you sued pre-petition,
21 and, again, you're describing to me fraudulent transfer.

22 If the debtor set this up so they could funnel the
23 money into a passive entity for purposes of protecting it,
24 perhaps there are claims against them for fraudulent
25 transfer, but, again, that is not your claim; that belongs to

1 the estate.

2 MR. MCCALLEN: So, thank you, Your Honor. I have
3 a couple of responses. I think it may be fraudulent
4 transfer. I also believe for the reasons I've stated, it
5 would also be a claim for unjust enrichment. And also, under
6 Copperweld, I think they would be included within a
7 coordinated enterprise.

8 Because, remember, Your Honor, the structure that
9 was put together was put together solely for tax reasons for
10 the debtors, and the debtors make a lot of that. They say
11 that we're suggesting that the structure, itself, was done
12 some nefarious reasons. That hasn't been our argument now.
13 I mean, obviously, it is later on. We found out through
14 discovery that it was done to protect assets in a certain
15 way, then maybe our view on that would be change.

16 So, we're not criticizing them for setting up
17 their business in a tax-efficient way, but what we're saying
18 is that when those decisions come down from the top, or at
19 least from the same place, wherever it's coming from in the
20 debtors' organization, because it's the same individuals who
21 are making these decisions -- it's employees of, you know, ST
22 Shared Services that do the work on the tax side for the
23 debtors -- you can't use this structure, which was done for
24 these tax-efficiency purposes, as a basis to when you get
25 into bankruptcy, to shield recovery from creditors.

1 And, Your Honor, it's not all creditor; it's just
2 certain creditors, and this is a really important point,
3 which when I talk about the leave to amend point, I'll hit on
4 it again, but I want to make it now. It's really important
5 that Your Honor understand, this effectively, the dispute
6 that's between -- Your Honor, this is between -- this is an
7 intercreditor dispute.

8 When these cases were filed, when the bankruptcy
9 cases were filed, they came in with a deal with the opioid
10 plaintiffs and certain other RSA parties, including the
11 bondholders, and then eventually there's going to be a
12 settlement with the government.

13 We've been very clear, and I want to be clear
14 about it, again, Your Honor, we are not challenging the
15 opioid settlement, and certainly by having our proofs of
16 claim filed against the Generics entity, we were not in any
17 way, Your Honor, and this is really true, we were not in any
18 way attempting to gum up the works on the Generics side of
19 the business for their bankruptcy.

20 But, Your Honor, what we are fighting about at
21 this point is the value that's left over and who's going to
22 get it, because under the debtors' proposed plan, you pay the
23 opioid settlement, you pay the Government, and you have a
24 very limited amount left over on the Specialty Brands side,
25 and so you've got to split it up amongst the unsecured

1 creditors. And the debtors have proposed a plan that gives
2 us claims only at two boxes, whereas the bondholders have
3 claims everywhere.

4 So, really, this is, effectively, an intercreditor
5 dispute between us and the other Acthar Plaintiffs and the
6 bondholders, about who, on the unsecured side on the
7 Specialty Brands, gets what's left over after you pay the
8 opioid settlement and after you pay the Government. That's
9 what this is really about.

10 But let me come back, Your Honor, because I just
11 want to make sure I hit any other points that I had. I think
12 I hit everything I had on the pleading standard.

13 Oh, there's one other thing I wanted to say.
14 Look, Your Honor pointed out the fact that the fact that are
15 in our objection are not in our complaint. I'm not going to
16 fight that. I can't. That was filed in 2019 before we knew
17 those facts but let me talk in the context of if Your Honor
18 feels that the pleading is insufficient, whether or not we
19 should, at this point, be given, granted permission to file a
20 motion for leave to amend.

21 And I think, Your Honor, it's clear that we should
22 for a couple of reasons. First, when looking at the
23 standards and the factors the courts will consider whenever
24 deciding to ultimate grant a motion for leave to amend -- I
25 understand Your Honor is just asking us now to argue whether

1 we should be permitted to do so, but I think looking at what
2 the ultimate standard will be is formative for the decision
3 in front of the Court now -- one factor is whether there was
4 a timely assertion of similar claims or demand evidencing
5 intention to hold the estate liable.

6 And I don't think they can reasonably contest that
7 there was a similar claim filed, such as the one we have
8 here. Obviously, if the Court determines that it's
9 insufficient or inadequate as a pleading matter, that's
10 another thing, but I think what this factor speaks to is,
11 again, this idea of notice, and they clearly had notice of
12 our claim.

13 Another factor the courts will look at is whether
14 other creditors would receive a windfall if the Court refused
15 to allow the amendment. And I think this goes to the point
16 that I was speaking to a few minutes ago, Your Honor, about
17 whether or not there would be a windfall.

18 In this situation, whenever you look at the
19 dynamics of the case, like I said, at this point, this isn't
20 about dipping into the pockets of any of those opioid
21 plaintiffs or the Government; this is a fight amongst
22 creditors on the unsecured side about who gets what left
23 over. And so, in terms of prejudice to the debtors, there is
24 no prejudice, Your Honor. This is a pot plan and so, you
25 know, we should be allowed to continue to litigate those

1 claims.

2 The reality is, and the equities of this are, and
3 I think the courts also will look at the equities when
4 deciding whether to grant leave to amend, the equities of
5 this are that Humana and the other insurers who have claims
6 in these cases are some of the largest payors into the debtor
7 structure for years. I've talked about the fact that Acthar
8 is its biggest drug, is its most profitable drug.

9 You know, these entities have paid billions of
10 dollars of claims and if we do have valid antitrust, RICO, or
11 other state law claims, if we do, and that'll be decided
12 later -- I'm not assuming it right now -- but if Your Honor
13 assumes that we do have valid claims, then it is only fair
14 and equitable that we have an opportunity to recover against
15 the entity that holds all of the different assets that those
16 -- that our proceeds supported for all of those years as part
17 of the debtors' Specialty Brands business.

18 In terms of the question about the reason for the
19 failure to amend and whether it would be equitable at this
20 point to allow us to amend, again, I just want to remind Your
21 Honor of the timing. I mentioned earlier -- I won't go back
22 to it -- but our pre-petition complaint. We got the
23 discovery in this case. We -- Mr. Harris said that we've
24 adjourned this hearing two times, he said, to allow us to
25 take more discovery. That's right in part. We did adjourn

1 it the first time because the debtors were producing
2 documents, a relatively limited universe of documents that
3 they said was are relevant to this motion, and so we pushed
4 it back a week to allow us an opportunity to review those
5 corporate organizational documents and to prepare to depose
6 Mr. Welch.

7 We took that deposition in mid-June, and we filed
8 our objection a week later. That was a pretty significant
9 undertaking to pull that information together within the week
10 and put the brief together that we did, but we did that and
11 we put that before the Court.

12 Thereafter, the debtor were set to file their
13 reply brief the following week and we were going to have a
14 hearing the following week, but it was set for the same day
15 as the proof of claim hearing that was going to be -- I'm
16 sorry -- the class claim hearing for Mr. Haviland's client
17 and we weren't going to get to it all in one day. So, we
18 agreed to extend the deadline for the debtors to file their
19 reply brief and, ultimately, we pushed even further because
20 Mr. Welch had, I believe he was out of the office last week.
21 We originally talked about doing it the 13th and we pushed it
22 to the 23rd.

23 So, this last month was extended, you know, for
24 reasons -- there was never any expectation or understanding
25 from the debtors' perspective that we were going to continue

1 to take discovery on this issue. We have always said, and I
2 recall saying this to Your Honor here in front of you on our
3 30(b)(6) motion for quash, we've always believed you cannot
4 disentangle the issues that the debtors put forward in this
5 motion, this objection, from the broader merits of our
6 claims. That's why we, right away, when we filed the
7 estimation motion, we sought that discovery.

8 And the debtors took the position on this motion,
9 on this objection, rather, they said, it's not relevant here.
10 The question is who actually did what, the merits of the
11 claim. That goes, if ever, to confirmation.

12 And then whenever we got in front of Your Honor to
13 argue for discovery on estimation, again, the debtor said,
14 that's for another day. You'll get that discovery later.

15 So, we were limited when we came in on this
16 objection to the universe of information that they said this
17 was about. And I told Your Honor back when we were in front
18 of you on the 30(b)(6) argument, I said, they're drawing
19 artificial lines and distinctions here, because you can't
20 disentangle, you know, documents about what the different
21 corporate entities are supposed to do or don't do, and who's
22 involved on that level from questions about who is involved
23 on a more substantive level, and do our claims have merit and
24 if so, in what boxes.

25 So, Your Honor, I just want to put that on the

1 record, because I believe that goes to the issue of the
2 reasons for the failure to amend. I appreciate Your Honor
3 understood that we were always going to move for leave to
4 amend. We thought the purpose of the objection, Your Honor,
5 was to tee up this dispute to the Court via a contested
6 matter, which we were obviously prepared to do today.

7 You know, if Your Honor believes that the
8 complaint does not withstand the standards of the first wrung
9 of Allegheny, then we think under the circumstances, Your
10 Honor, it would be fair and would not prejudice the debtors
11 to allow us to leave to amend. They know the facts. They
12 know what we're going to say. It's not like they have to do
13 anything new to prepare themselves for that case.

14 It's just a matter of them making us jump through
15 these hoops to try to prove-up the claims that, you know, we
16 have had and that they have known about for years. And it's
17 really just a question at this point about, do we get to --
18 if we have valid claims, because one way or another, we're
19 entitled to ultimately try to prove-up our claims. If those
20 claims are valid, do we get to go after the entities who are,
21 at the very least, involved in the Acthar-related conduct,
22 and maybe, ultimately, the entire Specialty Brands, or are we
23 stuck with ARD and PLC.

24 PLC is the parent company -- virtually no assets
25 in comparison to the overall enterprise value of the debtors,

1 and ARD, as well. ARD is an entity that has brought in
2 billions of dollars over the years from the sale of Acthar
3 and about 95 percent of it has been removed. And I'm not
4 saying it's a fraudulent transfer or anything like that, but
5 the reality is that what it reflects is that these entities
6 are treated as a single enterprise. And I use that word
7 because that's what the Copperweld Court talks about, it's
8 coordinated conduct amongst those entities by the same people
9 who largely sit in either officer or director positions in
10 most of the boxes.

11 And if it turns out that this Court decides, via
12 estimation or at confirmation or whenever it occurs, that we
13 have valid claims, both the equity and the law require that
14 we should be able to go at the boxes that have that value,
15 and that's what this is really about. Are we going to be
16 allowed to do that or is that value going to be allowed to go
17 to the other unsecured creditors of the Specialty Brands
18 business.

19 I don't have anything further, Your Honor. If you
20 have any questions, I'm obviously happy to answer them.

21 THE COURT: No questions. Thank you, Mr.
22 McCallen.

23 Mr. Haviland, before I go to you, we're going to
24 take a lunch break. So, let's recess until 12:45.

25 (Recess taken at 11:59 a.m.)

1 (Proceedings resumed at 12:45 p.m.)

2 THE COURT: Good afternoon. We're back on the
3 record.

4 Mr. Haviland, you may proceed.

5 MR. HAVILAND: Thank you, Your Honor.

6 It's a little difficult to close in a hearing when
7 the record hasn't been fully discovered and presented, so I'm
8 going to try to do so succinctly, based on all that you've
9 heard.

10 At the outset, I agree with Mr. McCallen on the
11 law. I think he adequately and appropriately explained the
12 Allegheny standard and we agree that it's not as robust as
13 Rule 12, which we faced no less than five times in the
14 underlying litigations. But at the outset, I want to address
15 a couple of open issues.

16 Number one, the Court had asked about the issue of
17 claiming against Brands and Generics and I just want to
18 reiterate that we, the ad hoc Acthar group, and, it is
19 important, Judge, to differentiate claimants. Too many
20 times, I think there's a one-size-fits-all with the debtors'
21 objections and they do toggle between our positions and our
22 claims in their papers, but I want to be crystal clear with
23 the Court that we make no claims against the Generics side of
24 the business. We haven't attempted to do so.

25 To the extent the debtors may point to a claim

1 against Mallinckrodt, LLC, which is in the Brands -- the
2 Generics side hierarchy, and I'll show in a moment, that the
3 substantial evidence that we have shows that Bill Hilmer
4 (phonetic), Hugh O'Neill (phonetic), and other executives in
5 the Brands business signed documents in the name of that
6 entity for Acthar. So, they can call it a generic today.
7 But it wasn't before, and when that changed is what discovery
8 is all about. So, I just want to be crystal clear, we are
9 seeking to claim only against the Brands entities that are
10 involved in and responsible for Acthar.

11 Number two, we did not file prophylactic proofs of
12 claim. We specifically demarcated those debtors whom we
13 believed were involved in Acthar. There's no footnote in our
14 proofs of claim that say we're unsure; we were very sure
15 about who we claimed against.

16 And we, unlike most claimants -- and we haven't
17 heard from Mr. Eisenberg, who has a declaration talking about
18 45,000 unsecured claimants who have zero value -- well,
19 that's not us. We had claims that had very clear addenda to
20 explain our position and had three attachments. Number one,
21 the complaint, and I want to pause on that for a moment just
22 to point out to the Court that the debtor has put into
23 evidence before you, Exhibit Numbers 9, 10, 11, 12, 14, 19,
24 20, 23, 25, 26, and 27, which are the complaints of the ad
25 hoc Acthar group litigants, and almost all of the orders

1 denying Mallinckrodt's motions to dismiss, both under Federal
2 Rule 12 in three instances and the State Court Rules in
3 Pennsylvania and Tennessee.

4 And that's important. I know Your Honor has
5 several times observed that Rule 12 isn't the end, but it is
6 at this point in terms of pleading. We have pled claims and
7 the debtors address antitrust, RICO, and unjust enrichment,
8 but they haven't addressed consumer fraud, which is in the
9 Pennsylvania cases, both before Judge Schuller in the federal
10 court, and in the state court case now before Your Honor, the
11 542 cases before you under the Pennsylvania UTPCPL. They
12 haven't addressed that at all, nor have they addressed fraud
13 or conspiracy, causes of action which have survived their
14 motions. So, they haven't attempted to demarcate their
15 position among the various claimants.

16 And then, finally, Your Honor made a comment about
17 bad faith and lack of support. If that was directed at us, I
18 respect the Court's observation, but we can't agree that what
19 we've attempted to do by providing that support was done in
20 bad faith. We, unlike, anyone, gave a damage model and a
21 quantification, based on actual purchases of Acthar. That's
22 our Exhibit B. Actual purchases. In fact, that so incensed
23 Express Scripts that they moved to suppress and put under
24 seal all of our claims, and they currently are all sealed.
25 No one can see them, except the Court and the debtors.

1 And then the third thing we did to substantiate,
2 and this is about substance, substantiate, we gave the
3 complaint that five judges have said it passes muster under
4 Rule 12. Then we said this claimant, and there are over 70,
5 this claimant fits this claim because there is an ASAP form,
6 Acthar support and access program form. Now, if you read any
7 of our complaints, we allege that beginning in 2007, that's
8 how this company changed the world. That's how they created
9 a distribution model, a marketing and sales paradigm that
10 allowed them to take the price from \$40 to nearly \$50,000,
11 the ASAP form.

12 And by showing the Court through our claims that
13 every single claimant had a beneficiary with one of those
14 forms, we took that claimant and put them within the
15 complaint. Now, that's the overarching approach.

16 I want to get to the issues that the Court raised
17 about these other entities and I want to walk through it a
18 little differently. I won't repeat the Allegheny standards.

19 I will point out that those Rule 12, the PO
20 rulings and the Tennessee ruling demonstrate that we
21 satisfied Twombly and Iqbal and that we did not group-plead.
22 And why that's important is because Mallinckrodt never made
23 that argument, even though we sued the PLC and ARD. They
24 never made that argument; Express Scripts did, and it was
25 rejected because, and counsel pointed out we've amended our

1 complaints because at times when the Court said, we want you
2 to differentiate your cause of action as between these
3 various entities, we didn't and as to the five Express
4 Scripts entities, we survived that.

5 We argued the single-entity doctrine of the
6 antitrust. Mallinckrodt did not. And we submit, Judge, the
7 law of the case which comes up to the claim is that they
8 don't get a do-over. They don't get to now say, we're not a
9 single entity, but that's what they're doing, but they're
10 doing it very carefully and very cautiously because they
11 don't want to create this situation where they have these
12 disparate corporate entities that can be sued. They want it
13 to be an enterprise, one PLC.

14 So, we take the entity as an enterprise, as one,
15 and I'll get to that in a moment. The evidence strongly
16 supports that, overwhelmingly supports that.

17 But even if you look at it the way they want you
18 to and break up this single enterprise into these buckets
19 that, yes, they existed in a federal filing to the SEC, but
20 nowhere do they say what the record in this case has shown,
21 is they took the Acthar function and business and broke it
22 up. Sent it to the U.K. Sent it to Ireland. Sent it to
23 Luxembourg.

24 Nowhere, and I'll show you why that's true, all
25 the documents are stamped highly confidential. No one gets

1 to see them. They don't put that business model out there.
2 They haven't cited you any evidence where it's publicly
3 available that MPL and MPIL had a collaboration agreement
4 over the Acthar business where all the decision-making was
5 done overseas. Nowhere has that been publicly divulged.

6 It only came in the last two months. It only came
7 through Mr. Welch who's on the camera right now, telling us
8 that's how it operated when he instituted DEMPE, D-e-m-p-e,
9 decision-making for the company, as a tax convenience, so
10 they get the benefit of Irish tax laws, the U.K. tax laws.
11 They toggle back and forth, moved functions when it
12 advantaged the corporation.

13 And I agree with Mr. McCallen, we're not saying
14 that was evil. They can do what's in their best tax
15 interests, but don't argue to us that because you've moved
16 function over there, we can't follow the money, as Your Honor
17 pointed out, and the function -- and I'll get to that in a
18 moment.

19 But even if they are independent entities, and we
20 don't accept that, we look at the independent entities as
21 potential co-conspirators. And there's a reason why single
22 enterprises don't argue this, because now, all of a sudden,
23 you've got a horizontal conspiracy. You've got an entity on
24 one plane that has functions, conspiring with one another to
25 set prices to have a monopolization on a product. Boy,

1 that's an interesting proposition the debtors want us to
2 have, that the PLC in conspiracy with the MPL and MPIL to
3 maintain the monopoly for Acthar by suppressing Synacthen, by
4 maintaining the distribution scheme. But if that's where
5 they want to go, that's where I'm going to go.

6 We say in paragraph 212 of the Rockford complaint
7 that beginning as early as 2007, the exact date being unknown
8 not plaintiffs, and continuing thereafter until the present,
9 the defendants and other unnamed co-conspirators between and
10 among themselves, entered into an agreement and, otherwise,
11 continuing conspiracy to cause my clients to overpay for
12 Acthar. The rest is laid out in the complaint, which five
13 courts, five, have found plead specific -- by the way, they
14 argued 9(b), not specific enough in time, place, and manner -
15 - rejected.

16 I don't think this Court can rule on what they're
17 suggesting without going into those court's opinions and
18 saying, I've looked at the pleading. We have tested it under
19 9(b). We tested it under group pleading. We tested it under
20 Twombly and Iqbal and it survived. It goes to the next level
21 of discovery, and that's important.

22 THE COURT: Well, Mr. Haviland, the complaints
23 that you're talking about were only against PLC and ARD, so,
24 to the extent the courts in those cases found that you
25 survived the Rule 12 motion, it's only as to those two

1 entities.

2 And in Delaware, the corporate structure is
3 sacrosanct and it is observed, unless proven otherwise. So,
4 you had an obligation to come forward in your proofs of claim
5 and allege facts that would show me and show the debtors that
6 there were claims against these other entities, other than
7 PLC and ARD. So, let's focus on that issue.

8 MR. HAVILAND: Certainly, Judge.

9 So, let's talk about the antitrust and let's talk
10 about the facts. I want to start with the fact that in a
11 price-fixing case, and we have that, the United States
12 Supreme Court said in 1898 in the Joint Traffic case, as
13 reiterated in the New Jersey case, 211 U.S. 1, there's a rule
14 of reason that requires the fact-finder to decide whether
15 under all the circumstances of the case, the practice imposes
16 a restraint.

17 And I point that out, Judge, because Judge
18 Capello, who ruled on this issue, said clearly that I am not
19 going to decide whether a rule of reason applies.

20 They're asking you to essentially accept
21 everything Mr. Harris said is true. Well, that's not the way
22 it works.

23 Everything we say is true in terms of conduct.
24 The judge did not decide whether it's per se -- by the way,
25 per se, if they fix the pricing, we get right to damages --

1 he said at Rockford, 360 F.Supp. 3rd 754, the Court need not
2 make this determination at this time. They're asking you to
3 make that determination right now, what standard applies.

4 Do you take this conduct, which was described? We
5 didn't know all the players and actors at that time.

6 And, Judge, I've got to point out an obvious
7 thing. Mr. Welch hasn't testified, but a company like Petten
8 Holdings, and I'll show you in a moment, a contract signed
9 June 2020, didn't exist until February of 2020. I would have
10 asked Mr. Welch this question: Mr. Welch, how is it possible
11 that the City of Rockford can sue an entity that didn't exist
12 until three years later?

13 Well, it's not possible. They created that
14 entity. They moved the distribution function out of ARD to
15 Petten Holdings. Now, how do we know about that?

16 We got the contract two months ago, not in the
17 underlying litigation where the Court ordered all contracts
18 to be produced, where Arnold & Porter reported to the Judge
19 that they had done it, repeatedly said they'd done it, and
20 they hadn't done it. That's a contract involving Acthar
21 distribution with Petten Holdings never produced. That's
22 Section 1.

23 Section 2, monopolization, and the judge in the
24 Rockford case, at 360 F.Supp. 3rd 755-56, points out that a
25 conspiracy to monopolize consists of a combination or a

1 conspiracy. We allege there was a conspiracy and there were
2 many actors, many of which we didn't know. We talked about
3 all the different entities with Express Scripts, but this
4 debtor never once said there are other actors.

5 They hid behind the enterprise of PLC and
6 represented repeatedly through discovery sponsor that
7 Mallinckrodt took the position. Now, the judge, at page 747,
8 described our claims as follows:

9 "The gravamen of the Plaintiffs' antitrust claims
10 is that the defendants acted and conspired to raise prices
11 exorbitantly high as part of a vertical price-fixing scheme."

12 Let me pause there. The price-fixing function has
13 moved. We did not know that. I deposed Mr. Hilmer. He was
14 asked by the FTC one month after DEMPE decision-making was
15 put in place, who and how is the decision-making on pricing
16 done?

17 He said, Mallinckrodt. He never said that MPL and
18 MPIL-n a collaboration agreement, decide that. They go up to
19 the executive committee of the PLC. That Mr. O'Neill has to
20 fly over there. He never said that.

21 Now, the Court is being asked to fault the
22 Plaintiffs for not doing our job, but what do you do when a
23 witness doesn't tell the truth? That was the FTC.

24 Two years later, in 2020 -- three years later -- I
25 asked him the same question. He said he testified truthfully

1 and never once under oath did he say, Mr. Haviland, I need
2 you to know something. It's July of 2020. We've had DEMPE
3 for a long time at this company. MPL and MPIL are deciding
4 all these things. ARD is insolvent.

5 We learned through the document in this case,
6 Project Easter, Project Gemini, Project Apollo, and a Project
7 Creed (phonetic), we don't even know what it's about because
8 it's all under privilege -- I'll show you the documents --
9 that they moved those functions out. Now, they did it for
10 tax reasons, but Your Honor said we get the following
11 conduct.

12 In the last two months, we've learned more than
13 we've learned in the last four years about how this
14 enterprise operates. They never told us that the entity that
15 we sued was insolvent. Insolvent. Couldn't write debt. Had
16 its debt-writing function taken away because it all got moved
17 overseas. And the Court is going to fault us for not asking
18 the right questions.

19 We never got to ask the senior (indiscernible),
20 Mr. Trudeau, Mr. O'Neill, Mr. Phillips, who was never
21 disclosed as a custodian, Dr. Romano, who I tried to depose
22 months ago. They constantly, constantly run interference and
23 argue with the blinders on that it doesn't relate to this
24 issue. They don't want to put these witnesses up because
25 it's their documents.

1 This company is only run by five to seven
2 executives, Judge. I can name them for you right now -- I
3 just did. They could have a hundred entities. It's a same
4 people.

5 If you read the SOFAs, it's Brian Reasons, Ian
6 Watkins, occasionally Mr. Welch comes in as executive
7 secretary. It's the same people, and why that matters is
8 because a part that they don't talk to you about when you
9 have Copperweld.

10 By the way, they never said Copperweld to us,
11 because that would have begged the question for the judge in
12 Rockford, all right, let's examine the PLC and the ARD and
13 whether they're conspiring with one another, parent and sub.
14 They didn't want to make that argument.

15 But here's what Copperweld actually says, and it's
16 out of Rockford in the context of ex Express Scripts arguing
17 that it should not be held liable for the acts of its
18 subsidiaries. Copperweld holds that the single entity cannot
19 conspire with itself, either with its employees or its
20 wholly-owned subsidiaries, 467 U.S. 769-770. I'm going to
21 read to you what the Court says, so you don't have to take my
22 word for what it says:

23 "The officers of a single firm are not separate
24 actors. There can be little doubt that the operations of a
25 corporate enterprise organized into divisions must be judged

1 as the conduct of a single actor."

2 Now, why is that important?

3 Because Mr. O'Neill, when he was deposed over in
4 the opioid case, said I don't treat these entities as
5 distinct entities. They're all just divisions. They're all
6 part of the same enterprise. And I'm going to read to you
7 what he says, and by the way, this is in the record, because
8 I finally got the deposition and we put it before the Court.
9 We didn't get his deposition, but we got the documents that
10 were produced in the opioid litigation. It's Exhibit 157 is
11 his CV and he was asked about and he says -- I'm trying to
12 streamline, Judge, and it's taking me out of order. I
13 apologize. I'll paraphrase. He says in his CV, and this is
14 -- he had just updated a month before he was deposed, that
15 there's one enterprise, there's one organization, and that
16 these other entities he was asked about, and he was asked
17 about SpecGX, the Generics company, but he was asked about
18 Mallinckrodt, LLC, the entity that wrote contracts involving
19 Acthar. I don't see those corporate forms. They're all
20 divisions.

21 And there's something that Mr. McCallen said that
22 I agree with, but I want to give a different flavor for.
23 This enterprise decided to create, instead of divisions and
24 departments like some entities do, Judge, they created
25 separate corporations: holding companies, operating

1 companies, cash pools. That's a different way to do it, but
2 the result is the same.

3 If they're operating as a single enterprise, you
4 don't get to break up your liabilities and move functions and
5 assets around, and if that's the position, then that's a
6 legal question for this Court and any reviewing Court going
7 down the road.

8 I want to go through, Your Honor, the proof, and
9 the proof being what we had and what we didn't have, because
10 that's really what is at the heart of the matter. It goes to
11 the underlying claims as they were stated and as to our
12 request for leave to amend. We put in the record, and,
13 Judge, I am just going to make an overall proffer that
14 defense counsel can respond to, the debtors' counsel, AHG1
15 all the way through AHG174, which consists of the debtors'
16 documents with the exception of a handful of Express Scripts
17 documents that the debtors didn't have and were pointing out
18 they didn't produce, because they're in the files. They're
19 documents that were shared between the companies but were
20 never produced.

21 Now, Express Scripts yesterday agreed we could
22 introduce those documents under the protective order in this
23 case, as long as they remained under seal. So, I wanted to
24 make sure that that is the proffer, that we're not asking
25 that they be put in the public record. But I want to walk

1 through that evidence, Judge, because when you review the
2 discovery that was conducted in the underlying litigation and
3 what's attempted to be conducted here, you get to the same
4 result.

5 We only knew what we knew and couldn't know what
6 we didn't know. And let's not lose sight of the fact, our
7 cases were stayed and we were enjoined. We were prevented,
8 because of the freezing spell, from taking any discovery of
9 either the debtors, third parties, or importantly, Express
10 Scripts to find out how the relationship had changed.

11 THE COURT: Well, that's not true, Mr. Haviland.
12 You had the opportunity to take 2004 discovery in connection
13 with this bankruptcy case.

14 MR. HAVILAND: Well, Judge, it's interesting that
15 you say that, because -- and my co-counsel, local counsel,
16 Dan Astin is on -- we sought 2004 discovery and Mr. Stearn
17 said we weren't entitled to it. He said that we had to work
18 through the UCC. We then contacted the UCC to find out about
19 producing discovery that they had. We just got that within
20 the last month or so. We have attempted to take 2004
21 discovery. We've been denied it.

22 THE COURT: Well, you should have brought that to
23 the Court's attention. It wasn't brought to my attention
24 that you were denied 2004 discovery.

25 And I'll point out that you did, in fact, join,

1 filed a motion to join the UCC's 2004 discovery and then
2 later withdrew it -- I don't know why -- but you withdrew
3 your 2004 discovery request to join the UCC.

4 And why you didn't get it up until now, again,
5 that's -- you know, you have an obligation to come forward
6 and notify the Court if you're not getting what you think
7 you're entitled to.

8 MR. HAVILAND: Well, Judge, we have repeatedly
9 tried to follow your Court's admonition to write and ask for
10 an audience. I don't think we've had an audience with you
11 till since months ago when I was called at five o'clock to
12 get on the call. Just this week we sought to have this issue
13 of the depositions decided and then the debtors filed a five
14 o'clock motion for a protective order that got moved to
15 today. So, we've attempted to do that, but we've been
16 unsuccessful.

17 I note that when the debtors write and ask to put
18 the Shenk motion off, it gets granted. We don't get to
19 comment on it. We don't get to talk about the implications
20 to the plan or our claims, but --

21 THE COURT: Hold on right there, Mr. Haviland,
22 because I left open that motion to give you the opportunity
23 to respond. You filed nothing in response to that, so that's
24 why I granted that motion.

25 Number two, you have never, ever, ever come to me

1 and said, we want 2004 discovery and the debtors are denying
2 it to us -- ever -- and if you had, I would have heard it.
3 So, don't put this on me, Mr. Haviland.

4 MR. HAVILAND: I'm not putting it on you, Judge.
5 I'm pointing out that if there are tactics, it's the debtors.

6 THE COURT: No, the tactics are yours, because
7 you're waiting until the last minute to then seek discovery
8 and then file motions to compel and that's what's screwing up
9 this process, not the debtors. You have an obligation to
10 move the case forward, as well as the debtors do. You have
11 an obligation to come forward if you're not getting discovery
12 and you didn't do it.

13 MR. HAVILAND: Judge, that is just not the case,
14 okay. We have, prior to this bankruptcy, aggressively sought
15 discovery --

16 THE COURT: I don't care what happened before the
17 bankruptcy, Mr. Haviland. I'm talking about what's happening
18 in this case.

19 MR. HAVILAND: Well, context is important, Judge,
20 because we're being faulted for what we knew about and didn't
21 do before October 12th. Let's not lose sight of the debtors'
22 position, that we should be faulted for all the little things
23 they have taken out of the record from the Rockford case,
24 which none of them say what I just said. They didn't produce
25 any of the 2020 contracts, the collaboration agreements, any

1 of those documents were produced, even they were squarely
2 asked for: all contracts, all communications.

3 We then asked again in this context and we're told
4 it's overbroad. When they represented to judges -- and not
5 just one judge -- that they had done it. Now, it's not these
6 lawyers. I noticed that Ms. Shores was on in her hoodie a
7 little while ago. It was Arnold & Porter. Repeatedly
8 reported to judges that they had done what they were supposed
9 to do.

10 You know, Judge, at some point in time, that is
11 going to have to be dealt with. And whether -- you know, the
12 bankruptcy can't stop a federal judge from dealing with
13 misrepresentations in their courts and those representations
14 were made to judge up in Rockford --

15 THE COURT: Mr. Haviland, I don't want to hear any
16 of this. I want to hear what happened in this court.
17 Because you have the opportunity to take 2004 discovery. You
18 did not do so. You joined the UCC's, but then withdrew your
19 joinder. You waited until just days before this hearing to
20 seek additional discovery and you haven't shown me any reason
21 why that discovery would have given you -- you've told me now
22 you have all this evidence, you have all this information
23 that would have allowed you to amend your proofs of claim,
24 but you didn't do it.

25 MR. HAVILAND: So, Your Honor, I want to tell you

1 about --

2 THE COURT: You lost your -- I can't hear you, Mr.
3 Haviland.

4 MR. HAVILAND: I, inadvertently, hit my mouse,
5 Your Honor.

6 So, Your Honor made a comment to Mr. McCallen that
7 you can look at the public filings and you can see all these
8 entities. Well, one of the first things that Judge Johnston,
9 as a magistrate, now a district judge in Rockford, ordered
10 even before the Rule 12 motions, he said, and he asked me,
11 Mr. Haviland, you know, if you had your wish list, what would
12 you like?

13 I said, Judge, I'd like the organization charts.
14 I'd like to see how this company is organized. And we put in
15 the record, Judge, at ECF 171, that order. That order was
16 2018. Produce all those organization charts so we can see
17 what they're talking about today. It was never done.

18 What was not produced, and I'm going to reel these
19 things off just so you can have the record for it, it was
20 never produced in response to that order.

21 THE COURT: If this is pre-petition stuff, Mr.
22 Haviland, I don't want to hear it.

23 MR. HAVILAND: No, Judge, it's Mallinckrodt
24 ACTH00000047, produced in this case. We have marked these as
25 AHAG61, a 2016 organization chart which shows how the Acthar

1 ARD business was moved from a top-line position directly
2 reporting into the PLC, all the way down to where it exists
3 right now as a defunct entity. That's AHAG Exhibit 61, page
4 47. If you go to page 44, it's the 2017 chart. If you go to
5 page 45, it's the 2018 chart. If you go to the next page,
6 69, it's the 2019 chart.

7 We never got the chart that Mr. Welch did at the
8 first day hearing which lays out all the debtor
9 organizations, because you have to go through the
10 machinations of all these moves to see how the Acthar
11 business was moved down, subordinated, and stripped of all of
12 its assets.

13 This company merged with QuestCor. It didn't
14 acquire QuestCor. They created the Mallinckrodt PLC as a
15 49/50 shareholder. We only had to sue the PLC, Judge.
16 That's all we had to do in 2017.

17 THE COURT: Again, it doesn't matter what you did
18 before the bankruptcy, Mr. Haviland.

19 What is at issue today is whether the proofs of
20 claim that you have filed against the debtors, other than PLC
21 and ARD, state sufficient facts to establish that there is a
22 claim against those debtors, and that's what I want to focus
23 on.

24 MR. HAVILAND: And I'm going to focus on that with
25 you, Your Honor.

1 Mallinckrodt has proffered as an exhibit, two
2 exhibits, that were marked in Mr. Welch's deposition, first
3 produced in this case --

4 THE COURT: None of those exhibits have been
5 admitted into evidence. I told you I wasn't having an
6 evidentiary hearing today.

7 MR. HAVILAND: Well, Judge, I'm making a proffer
8 now and I would like to offer them to be admitted. And
9 Exhibit 60 and 61 are the collaboration agreements signed by
10 Mallinckrodt Pharmaceuticals Ltd. and Mallinckrodt
11 Pharmaceuticals Ireland Ltd., and in that document just
12 produced in this case in the last couple of months, it
13 details how the function of Acthar, the decision-making on
14 manufacturing, distribution, pricing, marketing, and sales,
15 was moved between Ireland and the U.K.; those two entities.

16 That document was created October 1, 2016. It was
17 never produced in the underlying litigation. It was only
18 produced two months ago.

19 THE COURT: So, you had it two months ago. Why
20 didn't you amend your proofs of claim to add that to your
21 proofs of claim against these other entities?

22 MR. HAVILAND: Because two months ago, Judge, I
23 sought leave. May 21, I asked this Court for leave.

24 THE COURT: No, you didn't ask for leave. I went
25 back and looked at your -- you filed a motion to dismiss the

1 claim objection and in that, the only thing you asked for was
2 for leave to file a motion to amend later in the future and
3 you didn't do that.

4 MR. HAVILAND: Your Honor, that's why I ask you,
5 are we going to exalt form over substance?

6 Do you want a motion on that very issue when we
7 haven't had the issue of whether or not their objections have
8 been carried?

9 You know, it's a chicken-and-egg problem in my
10 mind, and I don't really practice in the bankruptcy arena,
11 but it seems to me that when we put forward a complaint that
12 has passed muster by five courts and talks about conduct, now
13 the debtor says, well, we broke up the band, Mr. Haviland, we
14 moved all of these functions around, Mr. Haviland, catch us
15 if you can, Mr. Haviland, figure out that we created entities
16 in 2020 that you maybe should've known about even though they
17 weren't described anywhere that they were doing Acthar, but
18 you should have done something about that, even though we got
19 documents two months ago.

20 So, I say in our response, and it's a group that
21 filed it, if that's true, then we seek leave to amend to
22 bring those facts to the Court.

23 Judge, if you're inclined to say under Rule 15
24 that the door is shut today, then just shut the door. I
25 don't think the Supreme Court or the Third Circuit says that

1 when it comes to Rule 15. We're supposed to be getting to
2 the facts and the truth. It seems to me we're just
3 getting -- it's a game of time and running out the clock.

4 These debtors have stonewalled us repeatedly and
5 if granted leave to file that motion, which I sought, and
6 we'll file it next week. I'm not looking to put this off.
7 We want that hearing on September 1, 2021, Judge. Let me say
8 that again: we want that hearing. But we want to get there
9 -- I know it's funny, Mr. Welch, but I don't think it's funny
10 -- we want to get there, because we want to be able to prove
11 our claims, okay. And we don't want to get caught in these
12 traps that you've got the discovery.

13 We did not get those collaboration agreements;
14 they were withheld. And if Your Honor doesn't want to look
15 at what the other judges ordered, that's fine; that's your
16 prerogative, I suppose, but in context of faulting us for not
17 asking the right questions at the right time, coming in, we
18 had.

19 What we also didn't know is all these projects,
20 which repeatedly talk about Acthar-function moving, and Mr.
21 Welch's deposition 13, MNK's Exhibit 62, Bates number 1558,
22 produced two months ago, Project Easter, how they moved
23 functions. And Mr. Welch repeatedly said it was for tax
24 purposes, but the fact is it's more than that.

25 In this context, they're saying, you don't get to

1 claim against them because we did this machination. And,
2 Judge, you should go through, and I'm proffering these
3 documents because I have them now, and today is the day,
4 Exhibit 62, Exhibit 55, Exhibit 56, Exhibit 57, Exhibit 58,
5 Exhibit 59, Exhibit 63 are all the projects produced by the
6 debtor two months ago, which it would take a team of people
7 to figure out what all of those corporate maneuvers mean.

8 We've barely scratched the surface with Mr. Welch,
9 in terms of all the different functions and move. What's
10 clear to me as I sit back, I see the PLC, I see MIFSA
11 (phonetic), I see CV. The two entities that financed Acthar,
12 not with anybody within Mallinckrodt, no, no, the documents
13 are clear, and they're in my proffer, the documents are
14 clear. They gave equity and they're out of the money, and
15 they took the borrowing capacity of QuestCor and financed
16 against it.

17 QuestCor came in as a billion-dollar enterprise.
18 By the way, they paid \$5.8 billion. At the time, this
19 company was only worth two. A two-billion-dollar company
20 buys a six-billion-dollar company. Who had the stronger
21 position?

22 So, MIFSA and CV created that debt instrument.
23 And, by the way, that's how all the general unsecured
24 noteholders are claiming now against everybody beneath them.
25 But if you look at those document, Judge, and they're in the

1 record, I'm proffering them, the PLC did not give any
2 guaranty to those noteholders, none. We sued the PLC.

3 So if you're going to look at these claims and we
4 can't discriminate among unsecured claimants, because we're
5 in the same position other than under the RSA they're getting
6 \$375 million and 80 percent ownership of the company. So
7 they are getting that. We are getting some share of \$100
8 million broken up among 64 different entities, most of which
9 have no revenue, no assets, no money, no function, but
10 somehow they're getting a share of that money and we're being
11 told you get a little share of ARD, an insolvent entity that
12 nobody knew about, and the PLC. Thank you very much, let's
13 all go home because if that's the way that is going to play
14 out then I think it's time for someone else to review it
15 because that to me just shows you what is going on here,
16 Judge. They took a company that was making a billion dollars
17 a year and they stripped it dry.

18 Now I want to point out our discovery so you can
19 have a clear record in terms of deciding whether to give us
20 leave to file a motion for leave. We have put in the record
21 the court's orders in Rockford's at A8-AG 152, 153 and 154.
22 We have put in the record our multiple discovery requests 1,
23 2, 3 and 4, AH 149, 148, 150 and 151. We have put into the
24 record correspondence between counsel for the City of
25 Rockford and Arnold & Porter about their discovery

1 deficiencies AH 157 and 155. We have also put into the
2 record, Judge, Mallinckrodt's custodian list in Rockford AH
3 156. You will find it interesting that people who were
4 talking about it are not on it. Mr. Phillips is not on
5 there.

6 Now Rule 26, I'm pretty sure, was amended a long,
7 long time ago where the defendant has to tell us the people
8 with knowledge. They didn't do it. In fact, we got a letter
9 on August 12th, 2019 right before Bryan Cave left AH 158
10 giving a very short list of people that did not include the
11 following important people that drive the decision making in
12 this company.

13 Kathy Schaefer, the president of virtually every
14 brand company sometimes Brian Reasons, Brian Reasons isn't on
15 there. Gary Phillips, the head of MPIL, who with Dr. Romano
16 makes all of the decision makings under the collaboration
17 agreement. Mark Tradeau, the CEO, is not on there. You know
18 who else isn't on there, Mr. Welsh the person most
19 knowledgeable in this bankruptcy; he's not on the list. It's
20 not our job to catch them, that is their 26 obligation. They
21 should have told us these people were relevant.

22 Now we got from the debtors a document that I'm
23 going to proffer, (indiscernible) 5, Welsh Exhibit 5, a
24 summary of legal entities and it purports to explain what is
25 a brand and what's a generic. The problem with that, Judge,

1 is the debtor decided what is brand and what is generic
2 without any regard to the history that I just told you about
3 that's in those documents. Mallinckrodt LLC, and I'm going to
4 go through them, clearly signed documents on behalf of this
5 entity that is the brand entity time and time, and time and
6 time again.

7 I want to point out another fact that is relevant
8 to the issues of whether or not we get to go after these
9 entities. There's two documents you put in, the Irish
10 statutory account filings, AHG 9 and 11, and a cover at 10.
11 In those filings, Judge, the brand entities exist in one
12 location. 675 James S. McDonnell Boulevard, Hazelwood,
13 Missouri.

14 One of the factors the courts look to is do they
15 have different offices. They have one. That is their
16 office. We didn't know that. We didn't know we shouldn't be
17 looking at all these other entities. All these now brand
18 entities that are working the Acthar business. The point is,
19 Judge, the person that knew this the most was never deposed.
20 He was ordered in Rockford to appear. The first time you and
21 I spoke was to quash that subpoena of Mr. O'Neill. He has
22 yet to testify. We deposed the people they put-up, Mr.
23 Hillmer, the executive assistant, Ms. Falconi, and Mr. Close
24 [sic], but that's it. That is all we got.

25 Why that matters, Judge, in the record we put in

1 the opioid litigation which these debtors are involved in,
2 AHD 63 and the pleadings that follow 62 which frame the issue
3 for Judge Polster about whether or not this PLC, whom we sued
4 -- by the way, I don't want to cast aspersions on anyone, but
5 none of the blues, the insurance claimants, sued anybody.
6 Let me repeat that, they didn't sue anybody. There is no
7 complaint.

8 So if you're going to judge claims in terms of
9 whose where in the pecking order we sued, we litigated
10 (indiscernible) 12, we framed the conduct that courts have
11 agreed with. Those blues entities they haven't explained why
12 they have a claim. Most of them, from what I can tell,
13 Judge, are third-party administrators. They don't even pay
14 for Acthar. They administer for my clients. It seems to me
15 that is a double DIP. Humana, and I'm not going to pick on
16 Humana, but they sued the PLC then dismissed the PLC. We
17 didn't. So we have claims against the PLC and ARD.

18 The reason why the judge, and I won't repeat the
19 citation to the unreported case of Judge Polster, he looked
20 at the plaintiffs' proffer and Mr. O'Neill's transcript which
21 was under seal, but it's at 171, he testified:

22 Question,

23 "What's your job?"

24 Answer,

25 "I am in charge of the brands. I am the executive

1 vice president."

2 Question,

3 "For what organization?"

4 Answer,

5 "Mallinckrodt Pharmaceuticals."

6 Let me pause there. There is no Mallinckrodt
7 Pharmaceuticals. You can look at that list there is no
8 entity called Mallinckrodt Pharmaceuticals. Every single
9 witness we deposed curiously said they work for Mallinckrodt
10 Pharmaceuticals.

11 He is then asked,

12 "What is the PLC?"

13 Answer,

14 "I believe that is the holding company."

15 Question,

16 "Who pays your salary?"

17 Answer,

18 "I don't know."

19 Then he goes onto say, when they were asked about
20 the PLC again, the entity we sued, "You think of it as all
21 one company, counsel," and I'm on Page 18 at Line 5, "Well, I
22 think about it as Mallinckrodt Pharmaceutical and then the
23 way I think about it there's subsidiaries attached to it."
24 That is the highest ranking officer in this company
25 testifying under oath that he thinks about it as one company.

1 What you are getting today, though is lawyers.
2 Latham & Watkins, Wachtell who were part of the original
3 merger agreement, they both represented those entities,
4 they're arguing to you now that it's different. They're not
5 letting the executives come forward, Judge, and testifying
6 under oath what I just read to you. Then he is asked,

7 "What do you do?"

8 Answer,

9 "The operational piece is run by myself and an
10 operating committee."

11 That is on Page 19. That is the record. In his
12 CV, and I pointed this out, its Exhibit 172 he says its "One
13 commercial organization." There is a franchise. The ARD
14 franchise. Then he talks about in communication with
15 outsiders including investors and key stakeholders the ARD
16 "division." He doesn't say Inc., LLC, he doesn't say it has
17 to go all the way up this hierarchy to get to MEH, to get to
18 the PLC. He says I am the highest ranking officer, it's a
19 division.

20 By the way, separate witnesses would depose Mr.
21 Kilper who is in finance. Mr. Welsh may know him. His
22 deposition is now in the record at 173. He says, again,

23 "Who do you work for?"

24 Answer,

25 "I work for Mallinckrodt."

1 Question,

2 "Which Mallinckrodt entity is your employer?"

3 Answer,

4 "I don't know. I work for Mallinckrodt."

5 Question,

6 "Who pays your check?"

7 Answer,

8 "I don't know."

9 Question,

10 "Where does the money come from?"

11 Answer,

12 "I don't know."

13 Then he talks about,

14 "What position do other executives, Mr. Harbaugh,
15 have?"

16 Answer,

17 "You're talking about legal entities. I don't
18 know."

19 Question,

20 "From an operational standpoint do you make
21 distinctions between the legal entities in Mallinckrodt?"

22 Answer,

23 "From an operational perspective I do not."

24 That is Page 12 of Exhibit 173. His CV says the
25 same thing at 174. Mallinckrodt Pharmaceuticals. This is

1 the evidence, Judge. You're now being shown this chart --
2 and I understand corporate law, we all get that in law
3 school, but these debtors are trying to hide assets and
4 liabilities, and shield an insolvent corporation. Judge, if
5 you read those projects that I read Easter [phonetic] and
6 Gemini we only found out that ARD was insolvent as of the
7 fall of 2018 from Mr. Welsh, insolvent. It had no ability to
8 write anything. Every single function got moved out; HR,
9 legal, finance, manufacturing, IP, research and development,
10 distribution, pricing, marketing, sales.

11 I want to turn to that right now and then I will
12 conclude. All those functions no longer reside in ARD, none
13 of them. We litigated the issue of the contract, the
14 exclusive distribution contract which is in the record. Your
15 Honor has seen it a couple times, Exhibit 170; it's the 2007
16 agreement signed by then Questcor. It was only amended 12
17 times and the last time was 2017, Exhibit 169.

18 I asked Mr. Welsh I that agreement is still
19 operative and he said yes. Here is the problem, we didn't
20 get these documents. There's a warehousing agreement signed
21 June 10th, 2020. It's produced in this case two months ago at
22 MK ACTH 1762. It's in your record, Your Honor, as Exhibit
23 53. We didn't get the transmittal from Wachtell, Exhibit 51
24 which was signed off by the MPIL organization. There it's
25 signed by Mr. Pio [phonetic], that's Exhibit 51.

1 We didn't get the bill of sale which transferred
2 \$561 million from ARD -- by the way, don't take my word from
3 it, the ARD SOFA in the record at 969, Docket 969, at 4.2
4 MPIL received \$561,654,617 as an intercompany commercial
5 chain transfer. That is why it matters. June that happened.
6 The bill of sale produced, which is Exhibit 52, references a
7 third amended and restated distribution agreement from
8 September 2019 between MPIL and ARD. It's a distribution
9 agreement.

10 I can't tell you how many times we asked for
11 distribution agreements because the lead document from '07 is
12 a distribution agreement, never produced. ARD document
13 signed with MPIL never produced. No excuse. There is an
14 assumption agreement MPIL where the operations were turned
15 over to SD Operations, a new entity. Judge, you don't have
16 any record in front of you, but if you look at our LEHB
17 complaint, and I put that in the record, that is the one we
18 filed for post-petition conduct, we detailed all these
19 entities and when they were formed. And most of the ones
20 we're going after were formed after Rockford sued.

21 So Exhibit 55 is the assumption agreement, never
22 produced. Exhibit 56 is the transmittal, never produced.
23 Exhibit 54 a distribution agreement, never produced. As to
24 the (indiscernible) operation manager is 59, never produced.
25 Exhibit 58 SD Operations transmittal, never produced. A

1 services agreement at Exhibit 82 -- by the way, these are all
2 in June of 2020, all signed in June of 2020.

3 Now we're to July, July 8th now all of a sudden we
4 see Petna Holdings [phonetic] signs an agreement with ARD,
5 this is Exhibit 2, and it seems to me, Judge, all the
6 functions get transferred out. ARD says it doesn't possess
7 the knowhow to do the things it's been doing since Questcor
8 did them in '07 and now all of a sudden they're getting
9 transferred by an entity that was formed in February called
10 Petna Holdings, Exhibit 2.

11 Exhibit 94, those functions are now transferred to
12 a company called SDE Services, never existed before 2020.
13 September 8th, 2020 that happened. September 8th, but we're
14 supposed to know that and sue SP Shared Services because of a
15 contract that was signed on September 8th.

16 I am going to just point out, Judge, that there
17 are a litany of documents that go to the issue of
18 Mallinckrodt LLC and the reason why I keep to this is if you
19 look down to what the debtors described as the brand side
20 business which goes from NIFSA, you've got CV, and then you
21 come down and you see NEH, a Nevada Corporation, which
22 historically was the entity that controlled all the US brand
23 business. It goes to the left, to the Mallinckrodt ARD
24 Holding Company and then it goes to the right, to the
25 generics. I'm sure Your Honor has seen the chart a number of

1 times.

2 THE COURT: Hold on one second, Mr. Haviland.

3 I've got a technical issue here.

4 MR. HAVILAND: No worries.

5 (Pause)

6 THE COURT: All right. I've lost my courtroom
7 camera, so I'm going to switch -- oh, now it's back. Never
8 mind. Go ahead, Mr. Hughes -- or, excuse me, Mr. Haviland.

9 MR. HAVILAND: I see Your Honor. I'm going to
10 finish up here. I'm trying to point out to the Court as
11 quickly as possible how the functions are moved. We walked
12 through distribution; we talked about the collaboration
13 agreement which deals with pricing.

14 I do want to touch upon R&D because, Your Honor,
15 when you rule denying our motion to compel, but granting
16 limited leave, you said follow the money -- and I'm going to
17 paraphrase -- but follow the function as well. Research and
18 development, an important part of this, had been transferred
19 in 2014, shortly after the merger. That document is revealed
20 by AHG No. 100, a document signed by MPIL and Mallinckrodt
21 ARD, Inc., the defendant in our case.

22 And I can't say it enough, Judge, if Arnold &
23 Porter were litigating with us right here, they'd say, yes,
24 we asked for it five different ways. It's not over-broad to
25 ask for the research and development services agreement, it

1 was only produced two months ago. That's how we know that
2 R&D got transferred.

3 Now, I did say I wanted to touch upon Mallinckrodt
4 LLC because there are a few entities when you look at those
5 projects that moved over from the brand side to the generic
6 side -- and they may be generic-oriented today, but they
7 weren't -- Mallinckrodt LLC is the one that stands out,
8 Judge, because repeatedly they signed contracts, beginning
9 with a document in 2015. That exclusive wholesale product
10 purchase agreement that we've described was modified by Todd
11 Killian, the vice president of market access for Mallinckrodt
12 LLC, using the same address on McConnell Boulevard up in St.
13 Louis. That's at Bates number 109.

14 Exhibit 34 is a rebate agreement signed by LLC;
15 Exhibit 35 is a distribution agreement with Caremark signed
16 by LLC; an inflation agreement signed with Express Scripts at
17 Exhibit 8, signed with LLC; Caremark again, Exhibit 36.

18 The rebate agreements, I think they say in their
19 papers that these are just isolated PBM agreements, they're
20 not. The distribution, the sales, and the financing in terms
21 of inflation and rebates are signed by Mallinckrodt LLC.

22 And by the way, Judge, the one I'm pausing on,
23 number 49, here's what the read says at the beginning, the
24 third amendment to the rebate agreement with Caremark,
25 "Mallinckrodt LLC, the manufacturer."

1 Now, these are legal documents. You've got -- you
2 want to respect the entity, I do. So if the LLC says,
3 Mallinckrodt LLC on the generic side says we are the
4 manufacturer of Acthar -- and, by the way, this is signed by
5 Hugh O'Neill, SVP President, U.S. Specialty Services -- I
6 take him at his word that they're the manufacturer.

7 Price increases, that's another important
8 function. That function got moved and the discussion begins
9 at Exhibit 20. And then there are a series of price
10 announcements, which we point to under the exclusive
11 agreement, where they announce the prices in concert with
12 Express Scripts. And these documents were all signed by
13 Mallinckrodt LLC, not ARD; 44, the December 2014 price
14 announcement; 73, the June 2015 price announcement.

15 And by the way, I'm glossing over, but each time
16 Acthar is going up thousands of dollars. In 2015, it went
17 from 32,000 to 34,000. On Exhibit 68, 2016 price increase,
18 it goes from 34 to 36,000. Exhibit 39, it goes from 34 to
19 37,000. All signed by Bill Hilmer, Senior Director,
20 Strategic Pricing and Contracts, Mallinckrodt LLC, not ARD.
21 And he was deposed and asked these questions.

22 I'm going to finish with a couple of other points.
23 The legal, which is a function. We've shown you, Judge, in
24 the prior issues with Arnold & Porter, there was one
25 engagement. And there was an issue about whether or not

1 Arnold & Porter represented all the different entities and I
2 think the ruling was, well, they can represent the
3 affiliates, but where a single entity engages one lawyer in
4 one engagement, well, that denotes the fact that it's one
5 single enterprise because they're going to do a conflicts
6 check. If they're different enterprises and Arnold & Porter
7 represents one and some other company represents another,
8 there may be adversity there. But those exhibits, 164, 165,
9 and 166 we'll maintain under seal, but that points out to us
10 that the company is acting as a single entity.

11 Finance, Mr. McCallen touched upon that, but the
12 cash management system was done through one function through
13 these holdcos. We put in the record Exhibit 7 and then,
14 importantly, the agreements, the master cash agreements at
15 Exhibit 5 from August of 2020, and Exhibit 6, it's September
16 2021. The signatories of all the different entities we're
17 talking about and their right to get cash, one person, Brian
18 Riesen signs for all those entities to give them the right.

19 My point being there's only a couple of people
20 that are running this entire company. The Mallinckrodt
21 Pharmaceuticals brand, undifferentiated, shows up in their
22 balance sheet, Exhibit 21 and 22. Their actual balance
23 sheets, if you look at all the money coming into the
24 organization and denotes it as Mallinckrodt Pharmaceuticals,
25 it doesn't put it in these different buckets, these cash

1 pools, it looks at it as an enterprise, money coming into one
2 organization, and then the organization reallocates those
3 monies.

4 Finally, Your Honor, we put into the record to
5 give you direction in terms of where we would go with an
6 amended pleading. Well, we've already done it. We filed a
7 complaint on behalf of the Law Enforcement Health Benefits
8 Fund, it's at Exhibit 168, that lays out these entities and
9 who they are and what they do. So the debtor has known about
10 that since May 26th, 2021. We sought leave to amend May 21,
11 but that pleading was filed, it's now in the record before
12 you.

13 And I'm going to finish with that, Judge. And I
14 want to loop in the committee because they filed a pleading
15 last night, it's at Docket 3316. And we have worked by and
16 through the committee, who is the committee for the general
17 unsecured creditors, including our group, especially our
18 group, our client sits as the chair. And as counsel now
19 knows -- we haven't had contact with her until this last week
20 -- because she has a fiduciary obligation to all creditors,
21 but the committee came out and took a position and I think
22 it's important, they said, "Since the commencement of the
23 cases" -- I'm at paragraph 1 -- "the UCC has worked
24 diligently to understand the enterprise threatening
25 litigation and how this enterprise works."

1 And the UCC's own independent analysis, quote,
2 "They cannot make sense of the debtors' assertion that the
3 private claimant, Acthar claimants' claim for liability
4 exclusively sits in ARD because the debtor entities were
5 involved in the debtors' Acthar operations."

6 This is their discovery. They got this discovery
7 with their professionals. That's their conclusion at
8 paragraph 3. And they're coming out and saying they can't
9 take a position at this point because they're not done their
10 work, but you're being asked to say shut the door on any
11 amendment. And I respectfully submit, Judge, there's only so
12 many different ways you can ask, but if it's going to require
13 a motion, we'll file it, we'll file it tonight. But to have
14 the debtors argue that you should not allow an amendment in
15 the face of all this evidence -- and I mean all this evidence
16 -- what was not produced in the underlying litigation, what
17 was dumped upon us in the last 60 days, and we said, if
18 you're going to look to that, Judge, and rely upon that,
19 then, please, give us leave to amend.

20 And maybe it was inartful to say we'll file a
21 motion -- or we want leave to file a motion, I'm amending
22 that now to say, Judge, we want to file a motion, because
23 Your Honor should not have to rule in a vacuum simply upon
24 proofs of claim that were filed February 16 which have this
25 bona fides to them. This company is committing antitrust

1 violations, RICO violations, consumer fraud, and it doesn't
2 seem like we're ever going to get that point. I'm not asking
3 you to litigate the underlying question, but you can't ignore
4 the fact that we have viable claims against the PLC and ARD,
5 and they want to shut the door as to everybody else by their
6 creation through some tax vehicle.

7 So we ask for leave to amend, Judge. Thank you.

8 But I want to admit these exhibits, Exhibits 1
9 through 174, and the Debtors' Exhibits that I've referenced,
10 because this is the hearing. I believe Mr. Murtagh said at
11 the beginning, now is the time. That's my proffer and I ask
12 the Court to admit them.

13 THE COURT: All right. You've made your proffer,
14 but I'm not going to admit them into evidence at this time.

15 Mr. Harris?

16 MR. HARRIS: Thank you, Your Honor.

17 We are not here to discuss whether there are valid
18 claims against ARD or PLC. We do not object to them for
19 today's purposes. We're here to determine whether these
20 proofs of claims against the non-defendant debtors are
21 sufficiently alleged. All these claimants chose not to
22 amend, that was their call. Collectively, what you heard is
23 one single attempt to defend the existing proofs of claim,
24 that is attestor saying that this is just a notice pleading
25 standard. That's not an answer.

1 The standard under Allegheny is, quote, "The
2 claimants must allege facts sufficient to support the claim."
3 There's no dispute they allege no facts as to any non-
4 defendant debtor.

5 And as to notice pleading, the proofs of claim do
6 put the debtors on notice of alleged conduct of ARD and PLC,
7 but there's no notice of alleged conduct by any non-defendant
8 debtor, there's no notice of what facts supposedly make these
9 debtors liable. So there is -- you've heard no real defense
10 of these proofs of claim. All this discussion is really
11 about is the plea about whether the disallowance of these
12 proofs of claim should be with prejudice or not.

13 So what did you hear to support essentially the
14 request to allow them to amend that is extremely late? Well,
15 attestor said a bunch of things about what they believe some
16 of the non-defendant debtors did. And I guess they did that
17 to preview what their amended proofs of claim would say in
18 order to encourage allowance of this late amendment. But if
19 you listen to what they said, everything they said is clearly
20 insufficient. None of the activities they mention that they
21 say these other entities did are the alleged wrongful acts
22 here. None of them are what they claim to be the tortious
23 wrongful acts.

24 They said some debtors were involved in
25 manufacturing Acthar. Well, there's nothing wrong with

1 manufacturing Acthar. The second category, some defendants
2 are engaged in R&D of Acthar. There's nothing alleged to be
3 wrongful about R&D of Acthar. They said some are engaged in
4 distribution, but what you didn't hear is that any of these
5 entities are engaged in the only supposedly wrongful part of
6 the distribution, which is the exclusive CuraScript
7 distribution contract. If you look at the proof of claims
8 and you look at what you heard today, that contract is only
9 with ARD.

10 So what did you really hear is that other entities
11 benefited from the proceeds of Acthar. That is insufficient
12 as a matter of law for all of these claims. I noted the
13 cases holding that as black letter law under antitrust law,
14 RICO, unjust enrichment. You heard nothing in response, not
15 one case other than a discussion of Copperweld. But what
16 Copperweld just says is that affiliates share a state of
17 mind, but you still have to allege that each affiliate
18 engaged in antitrust conduct, and that's what all the cases I
19 went through in my opening support. There are no cases that
20 support this theory that just because revenue goes to an
21 affiliate that affiliate is directly liable for antitrust,
22 RICO, or unjust enrichment, you heard no case in response.

23 When are they going to come forward with a case
24 that supports these theories? Well, today was the day. They
25 filed -- they each filed two different briefs in response to

1 this -- to our objection. There is not one case they cite to
2 support that the mere receipt of revenue by an affiliate is
3 enough for direct liability under any of their theories.

4 We have had enough delay, it is time to let these
5 issues be decided.

6 In terms of what you also heard is that there's
7 overlapping employees or that some employees view
8 Mallinckrodt as operating as one entity or as one business.
9 That's not an argument for direct liability. I'm sure you
10 will hear that in the context of substantive consolidation or
11 veil piercing, but there's not one case that you heard that
12 supports that those facts would create direct liability under
13 any of these theories.

14 You heard Mr. Haviland mention that there have
15 been prepetition motions to dismiss, some granted, some
16 denied, but of course none of those were claims against the
17 non-defendant debtors. No court has ever said that the
18 allegations in those complaints are sufficient to support a
19 claim against the non-defendant debtors.

20 You heard him mention consumer fraud claims. That
21 wasn't mentioned in any of the briefs he filed and in fact he
22 admitted in response to his interrogatories -- or the City of
23 Rockford did that the City of Rockford had no contact with
24 any non-defendant debtors. It's hard to see how that would
25 substantiate a fraud claim against those entities if they

1 never even communicated.

2 You also heard the ad hoc group a mid-level
3 employee, Mr. Bill Hilmer, as supposedly perjuring himself.
4 That is outrageous and there's no basis and it's
5 inappropriate to do live in a courtroom like that.

6 The other thing you heard was talk about shifting
7 of corporate assets. Well, that is a fraudulent conveyance
8 claim and, if it's supported and they want to argue it, or if
9 they want to argue for veil piercing in response to
10 confirmation, you will hear it then, but it is not a direct
11 claim they can bring.

12 What is really going on? Well, you heard the
13 truth. They want to go against entities other than the ones
14 that they actually substantiated a claim against because the
15 entities that they did put details about those things against
16 they believe are now valuable and they're worried about value
17 having shifted out of those entities. That is fraudulent
18 conveyance.

19 So they've had materials before the bar date that
20 would have allowed them to state facts about these entities.
21 They have the 10-Ks that list every subsidiary in Schedule
22 21, just like every 10-K does. Our organization chart was
23 part of the first day filing. The IP restructuring memo we
24 filed in November 2020 said who owns the Acthar IP, what
25 entities it was licensed to, and who paid and received

1 royalties. Why was not in that in the proofs of claim they
2 filed months later?

3 You heard both sets of claimants run through all
4 the evidence that they now have, but they've had that for
5 months. Why didn't they amend their proofs of claim? There
6 is no excuse provided by either of them why they did not
7 amend before this hearing. No one has explained why they
8 didn't pursue Rule 2004 discovery before the bar date, no one
9 has explained why they didn't incorporate what they knew
10 about these other entities before the bar date, and no one
11 has explained why they didn't amend the proofs of claim after
12 the bar date and before this hearing. They have known from
13 day one that they have to substantiate their claims against
14 each debtor. They could have amended and it is extremely
15 prejudicial to the debtors and to this restructuring for this
16 late amendment to happen now. They would have to file a
17 motion to amend, we would have to hear it; we would then have
18 to redo this hearing with their newly amended proofs of
19 claim. If those in fact were to survive, we would then need
20 to have an estimation process perhaps and a hearing on that.
21 All of that pushing back and prejudicing the estate, the
22 other creditors, and this Court.

23 It is too late, it is too prejudicial. They
24 should have acted in the way in which the rules require, they
25 should have supported their proofs of claim when filed or

1 they should have amended them when they had the information
2 to do so.

3 With that, I'll pause.

4 THE COURT: Thank you, Mr. Harris.

5 All right, I'm going to take a recess so I can
6 consider the issues. We'll recess until 3 o'clock. I'll
7 come back on and I'll give you my ruling at that time.

8 (Recess taken at 1:55 p.m.)

9 (Proceedings resumed at 3:03 p.m.)

10 THE COURT: All right, this is Judge Dorsey. We
11 are back on the record. I'm going to give you my ruling on
12 the motion to dismiss the unsubstantiated claims.

13 Retired Judge Gross once wrote that "the bar date
14 is important to the administration of a bankruptcy case as it
15 brings certainty to the debtor's case by enabling the debtor
16 and its creditors to know the amount of claims that exist.
17 It is akin to a statute of limitations and must be followed."
18 That's In re Nortel Networks, Inc., 573 B.R. 522 (Bankr. D.
19 Del. 2017).

20 It's plain to me based upon a review of the proofs
21 of claim at issue and the objections, as well as the parties'
22 pleadings and the arguments presented today, that those
23 claims were filed with a complete disregard for whether or
24 not any claims actually existed against those debtor entities
25 and in some instances with actual knowledge that either no

1 claim existed or likely existed at all. The strategy was
2 obviously: file proofs of claim against as many debtors as
3 possible in a corporate structure, assert that the proofs of
4 claim constitute prima facie evidence of the validity of the
5 claims, force the debtors to object due to the destruction
6 caused to the debtors' plan of reorganization process,
7 thereby gaining leverage against the debtors, then seek
8 discovery on the claims in the hope of finding facts to
9 support them. Those actions constitute bad faith and an
10 abuse of the claims process established by the bankruptcy
11 code and the bankruptcy rules. Therefore, I will sustain the
12 objections to the claims and they will all be dismissed.

13 The proper procedure here, as I stated at the
14 beginning of this hearing, would have been to seek Rule 2004
15 discovery, seeking information on whether or not potential
16 claims existed against any of the debtors other than
17 Mallinckrodt PLC or Mallinckrodt ARD, claims against which
18 the debtors are not objecting, prior to the filing of the
19 proofs of claim. For whatever reason, neither of the Acthar
20 groups chose that path.

21 The bar date order was entered on November 30,
22 2020, setting a bar date of February 16th, 2021, giving the
23 Acthar claimants 78 days to investigate whether or not they
24 had claims against any other debtor entities. The only
25 parties that sought 2004 discovery were the UCC and the OCC.

1 The insurance claimants didn't join the UCC discovery until
2 March 16th, 2021, a month after the bar date. The Acthar
3 group didn't join until March 3rd of 2021, again, after the
4 bar date, but later withdrew that joinder for reasons that
5 are perplexing to me.

6 The proofs of claim as filed failed to assert
7 facts sufficient to support claims against the debtors.
8 Therefore, those proofs of claim do not meet the sufficiency
9 requirements under the Third Circuit's decision in Allegheny
10 International 954 F.2d 167, 173, a 1992 decision.

11 The proofs of claim only assert claims against PLC
12 and ARD, with in some cases vague references to alleged
13 unknown co-conspirators and in other instances where they
14 outright admit that the proof of claim is being filed, quote,
15 "out of an abundance of caution," close quote, just in case
16 they do have claims that can be substantiated through
17 discovery. Those types of allegations are not sufficient to
18 put the debtor, the Court, or the parties in interest on
19 notice of a claim.

20 I will note that, despite the failure to seek 2004
21 discovery prior to filing the claims, the debtors did engage
22 with discovery with the claimants after the objection had
23 been filed, and I made rulings on that discovery indicating
24 what was permissible and what was not permissible.
25 Interestingly enough, that was in connection with a motion

1 brought by the debtors for a protective order, not a motion
2 to compel brought by the parties -- the claimants. Neither
3 group sought a motion to compel discovery, believing that
4 they had -- that the information that they were seeking was
5 being withheld. They waited until the Acthar -- the ad hoc
6 group waited until just days before this hearing to seek a
7 motion to compel, which was too late. Instead, the Acthar
8 plaintiffs simply rested on their proofs of claim as filed
9 and attempted to argue new facts in their responses to the
10 objection.

11 Those responses do not qualify as motions to amend
12 and I do not find that any of the facts alleged in the
13 responses somehow modify the proofs of claim as filed. If
14 the claimants believed that they had uncovered facts that
15 would allow them to amend, they should have filed the
16 appropriate motion and I could have evaluated those motions
17 under the appropriate standards for amending a proof of
18 claim.

19 Now, the ad hoc group claims that they requested
20 leave to amend in their motion to dismiss, but, as I noted
21 previously, all they asked for was leave to file a motion for
22 leave to amend, not asking to amend the actual complaints --
23 or, excuse me, proofs of claim, and that would require me to
24 engage in a factual finding that simply was not before the
25 Court at this time.

1 So even if I granted a motion to leave at this
2 time, because I find that the proofs of claim as filed fail
3 to state any claim whatsoever against the debtor entities,
4 motion to leave would actually be akin to a motion to file a
5 late claim. And as noted in the Enron decision of the
6 Southern District of New York, "the decision to grant or deny
7 an amendment to a timely-filed proof of claim rests with the
8 sound discretion of the bankruptcy judge." That is In re
9 Enron Corp., 328 B.R. 75 at 86, a 2005 decision.

10 The court went on to say it's important to make
11 sure that the amendment is not in actuality a new claim and,
12 given that no claims were asserted against the debtors in the
13 proofs of claim that I am dismissing, any amendment at this
14 point would in fact be a new claim against those debtors.
15 Because it is a new claim, it would require use of the
16 excusable neglect standard in Pioneer. And, as Judge Gross
17 noted in the Nortel decision, "Courts take a hard line when
18 applying Pioneer," and particularly in emphasizing the reason
19 for the delay.

20 I'll also make a note here on the Rule 15 relation
21 back because that was raised by the ad hoc group. Relation
22 back only applies under Rule 15 not -- does not apply, I
23 should say, to adding a party, but only to amendments to the
24 party against whom the claim is asserted. Well, again,
25 there's no claims asserted here, so Rule 15 would be

1 inapplicable.

2 So what's the standard under Pioneer for allowing
3 a late-filed claim? You have to show excusable neglect. And
4 the factors are you have to show danger or prejudice to the
5 estate; length of delay and impact upon judicial proceedings;
6 the reasons for the delay, including whether it was within
7 the reasonable control of the movant who acted in good faith;
8 and all of those factors have to be balanced. And it's Hefta
9 v. Official Committee of Unsecured Creditors, In re American
10 Classic Voyages Company, 405 F.3d 127 at 133 (3d. Cir. 2005).

11 In this case, I find that allowing the filing of
12 the late-filed claims would not comply with the Pioneer
13 standard. It would require an estimation hearing to
14 determine the validity of those claims, extensive discovery
15 on the merits of those claims that would take months and
16 would be followed by a days-long, if not months-long,
17 evidentiary hearing before the debtors could move forward
18 with their confirmation. That clearly has an adverse impact
19 on these cases, particularly in light of the fact that I
20 believe the debtors have indicated to me in the past the cost
21 of this bankruptcy is about \$20 million a month.

22 It's been nine months since these cases were
23 filed, eight months since the bar date notice went out,
24 almost six months since the bar date passed, with no attempt
25 to seek to amend the proofs of claim. Allowing late-filed

1 claims now would have a significant impact on these cases.

2 The reasons for delay also do not favor allowing
3 the late-filed claims. The movants never asked for 2004
4 discovery before the bar date, they never moved to compel
5 discovery they claimed was not forthcoming. And, curiously,
6 Mr. Haviland went through a litany of documents that he
7 wanted to introduce into evidence that he indicated were
8 produced two months ago. And yet, again, no motion to amend
9 was filed.

10 So it's clear to me that these proofs of claim do
11 not meet the standard for allowing an amendment, so I will
12 dismiss them with prejudice at this point.

13 All right? With that, Mr. Merchant, do we have
14 anything else on the agenda for today?

15 MR. MERCHANT: Thank you, Your Honor. I believe
16 two other things. First of all, I think the debtors and some
17 of the other parties had filed motions to leave in -- I mean
18 motions to seal in connection with the various pleadings
19 related to the unsubstantiated claim objection. I don't
20 believe there's been any objection to any of those motions,
21 though, consistent with the local rules, the objection
22 deadlines were set for this hearing.

23 So, unless Your Honor has any concerns, you know,
24 I would propose having the parties just upload orders with
25 respect to each of those procedural motions.

1 THE COURT: I don't have any questions or
2 concerns. Does anyone else wish to be heard on that issue?

3 (No verbal response)

4 THE COURT: Okay.

5 MR. MCCALLEN: Your Honor, and --

6 THE COURT: Oh, go ahead, Mr. McCallen.

7 MR. MCCALLEN: I'm sorry, Your Honor. I think
8 it's actually the issue we just covered a minute ago. I
9 understand Your Honor's order, but just for purposes of the
10 record, can we consider that Your Honor has read the decision
11 on the record and that's so order and there won't be a final
12 written order of any sort, and we can proceed from there from
13 today's record?

14 THE COURT: Is there any objection to just having
15 it so ordered on the record or do you want to have a written
16 order submitted under seal? I'll open it up, if anybody has
17 a preference.

18 (No verbal response)

19 THE COURT: All right, nobody has a preference.
20 All right, so I will just so order the record.

21 MR. MCCALLEN: Thank you, Your Honor.

22 MR. MERCHANT: Thank you, Your Honor. So, getting
23 back to the motions to seal, may we proceed in the manner in
24 which I proposed?

25 THE COURT: Yes, nobody has an objection. I don't

1 have any problem with them, so I will -- if you want to
2 upload those orders, we'll get them entered.

3 MR. MERCHANT: Thank you, Your Honor.

4 The one remaining matter that was on the agenda
5 for today was the debtors' preliminary objection to Humana's
6 motion for substantive consolidation of these cases. I know
7 that there was an agreement that that would go forward today
8 and Keith Simon from Latham & Watkins will be addressing that
9 on behalf of the debtors.

10 THE COURT: All right. Mr. Simon?

11 MR. SIMON: Good afternoon, Your Honor. It's
12 Keith Simon of Latham & Watkins for the company. Can you
13 hear me okay?

14 THE COURT: I can. Thank you.

15 MR. SIMON: Great. So, Your Honor, before we get
16 into the details of Humana's request for an August 24th
17 stand-alone sub-con hearing, I'd like to explain at a high
18 level how I see this playing out.

19 First, I'm pleased to report that we've resolved
20 our issues with the OCC. They agree with us that there's no
21 need for a separate stand-alone sub-con hearing, and I
22 believe someone from Akin Gump will be reading some
23 statements on the record to confirm our understanding. They
24 previewed that with us and we're on board with the concepts
25 that they're going to lay out.

1 So, Your Honor, as everyone knows, our Chapter 11
2 plan does not contemplate substantive consolidation; rather,
3 it respects the prepetition boxes and allocates value based
4 on the assets and liabilities of those separate boxes. So we
5 have teed up the issue. As part of our case in chief during
6 the confirmation, we will show why respecting those boxes is
7 appropriate under Section 1129 of the code. And if we can
8 show that the boxes can and should be respected, then by
9 definition we defeat and moot on the merits that the boxes
10 should not be respected for whatever reason. Consolidated,
11 merged, ignored, overlooked, pierced, it doesn't matter what
12 the basis is, they're either respected or not, because those
13 are mutually-exclusive positions.

14 And so our resolution with the committee, which
15 they'll read on the record, is that for a confirmation
16 objection, for them or anyone really to be able to argue the
17 boxes shouldn't be respected, for whatever reason, A, B, and
18 C, you don't need standing for a confirmation objection, you
19 don't need standing -- or to file an adversary proceeding to
20 make those arguments. But, again, they're just confirmation
21 objections, they're not stand-alone causes of action, they're
22 not stand-alone proceedings.

23 The committee was concerned that they would have
24 to jump through a bunch of hoops just to say the magic words
25 "alter ego," they don't. They can raise that as confirmation

1 objections, but that's all they are.

2 So, to be clear, people can file whatever
3 confirmation objections they believe are appropriate and we
4 will respond to those on the merits when it comes to
5 respecting the boxes.

6 So, Your Honor, I did just want to raise a couple
7 of issues that Humana asserted about the need for an August
8 25th sub-con-only hearing. First, in paragraph 11 of their
9 reply, they say sub-con will have a substantial impact on
10 plan negotiation and confirmation issues, so those should be
11 heard first. Well, Your Honor, you could say that about any
12 number of confirmation issues. Best interest tests,
13 feasibility, unfair discrimination, a channeling injunction,
14 releases, all of those have a substantial impact on the
15 process, that's why they're heard together. And since we're
16 the plan proponents, to be honest, we would like to present
17 our arguments in the way that gives us the greatest chance of
18 success. We think that is our right, unless Your Honor has
19 different views, that we should present the arguments in the
20 way that we think is most appropriate and it's not up for a
21 creditor to say this should be decided first, unless Your
22 Honor has preferences on the order we present arguments.

23 We of course believe an August hearing is a waste
24 of time because sub-con is inappropriate and we will deal
25 with the merits at the confirmation hearing.

1 The second point they make -- and this is the last
2 point I wanted to respond to -- is they say, you know, what's
3 the harm? We're all doing all of this discovery, there's no
4 prejudice, so let's just have the hearing in August. Well,
5 as my litigators will tell you, we're doing all of this
6 discovery, all of the documents, all of the emails, all of
7 the depositions, all of the expert reports for a confirmation
8 hearing scheduled September 21st, not August 25th, and you
9 can't separate sub-con from these other issues because it --
10 sub-con goes to where do assets and liabilities sit. That is
11 fundamentally going to impact best interests and unfair
12 discrimination at a minimum. So you can't just say this
13 disclosure statement is only for sub-con, it's relevant to
14 all of these confirmation issues, which is why you can't
15 slice and dice all of the discovery. We're doing all of this
16 now for a September 21st hearing, not August 25th.

17 So, with that, Your Honor, I believe that covered
18 my points that we will address the boxes as part of our case
19 in chief and people can object on whatever basis they want as
20 confirmation objections. So, unless Your Honor has anything
21 for me, I'll turn the podium over I think to Akin Gump and go
22 from there.

23 THE COURT: All right. Who's speaking for Akin?

24 MR. HURLEY: Your Honor, Mitch Hurley with Akin
25 Gump on behalf of the OCC.

1 THE COURT: Okay. Go ahead, Mr. Hurley.

2 MR. HURLEY: Thank you. So, Your Honor, Mr. Simon
3 I think has accurately described the nature of our agreement
4 in broad strokes. I do want to provide just a bit of context
5 that I hope will eliminate why the OCC filed its statement in
6 the first place and the significance of the agreement that it
7 believes it's reached with the debtors.

8 So, as the Court is aware, the deadline for
9 parties to file objections to the plan is September 3rd. As
10 Mr. Price outlined for the Court on June 16th, while the
11 OCC's investigation is ongoing, at present the OCC believes
12 that the plan may substantially under-compensate opioid
13 creditors on a number of grounds, and the OCC is considering
14 a number of potential arguments it may raise in connection
15 with objecting to confirmation of the debtors' plan. That
16 process is not complete and we don't know yet exactly what
17 form the OCC's objection, if any, will take, but certainly
18 the OCC's intention always has been to raise all arguments
19 and objections it may have to the plan at confirmation rather
20 than by some separate motion or in some separate proceeding.

21 Among the potential grounds we're considering is
22 investigating whether doctrines like substantive
23 consolidation, or alter ego or agency or veil piercing, might
24 be applicable in these cases in a way that would render the
25 plan un-confirmable. We've sought discovery on these points

1 and intend to continue to take discovery on these points.
2 But certainly to the extent that we determine to raise
3 arguments like that, it has always been the OCC's intention,
4 as I said, to raise those kind of points at confirmation and
5 in a manner and at a time that's consistent with the schedule
6 and protocols that have been entered by the Court already.
7 So that would include in the OCC's written plan objection,
8 which currently is due on September 3rd, and that I think
9 brings us to where we are now.

10 As you know, the Acthar insurance claimants moved
11 the Court for an order substantively consolidating the assets
12 and liabilities of certain debtor entities and set a hearing
13 on the motion of August 25th. The debtors filed their
14 preliminary objection, arguing the motion to consolidate
15 shouldn't be heard on the 25th and, among other things, they
16 argued that a creditor can't seek an order to substantively
17 consolidate debtor estates without first obtaining derivative
18 standing to do so and filing an adversary complaint.

19 The debtors' procedural arguments drew the
20 attention of the OCC because, as I just got through
21 explaining, we're considering raising arguments of that kind
22 in objection to the debtors' plan. If we do invoke sub-con
23 or other doctrines of the kind mentioned in the debtors'
24 papers -- and that's still an if -- the OCC may do it in a
25 way that's very different than proposed by the Acthar

1 plaintiffs who seek to substantively consolidate only a
2 subset of the debtor entities.

3 But for now what the OCC is concerned about is
4 really only that we're going to be relying on theories of
5 that kind as bases for objecting to the plan at confirmation
6 if we determine it's appropriate to so object, even if we
7 don't first file a motion either in connection with a
8 contested matter or obtain derivative standing.

9 We were first reassured by some statements in the
10 debtors' papers that suggested they agreed. You know, they
11 argued that it would be wasteful to go forward on the 25th in
12 part because it's inevitable that issues like sub-con will be
13 litigated at objection to confirmation, whether named
14 substantive consolidation, alter ego, or veil piercing, that
15 was reassuring. During a subsequent discovery meet-and-
16 confer, the debtors took a different position and that's why
17 we filed our statement is really we just wanted to make sure
18 that we got clarity, if possible.

19 Now, the debtors had taken the position in meet-
20 and-confer conversations that in fact we wouldn't be allowed
21 to argue sub-con or any of those other doctrines at
22 confirmation without making a motion first. As we explained
23 in our papers, that's not the OCC's view of the law. We
24 believe that those kinds of arguments absolutely can be
25 raised validly as plan objections and that, for example, just

1 to be really clear about what we mean by that, the OCC's view
2 is, if it were to persuade the Court in connection with
3 confirmation that debtor entities are subject to substantive
4 consolidation and that, as a result, the plan does not
5 satisfy aspects of Section 1129 because, for example, in a
6 sub-con scenario, opioid creditors arguably would be entitled
7 to more consideration than contemplated under the plan, the
8 OCC would contend that would be an absolutely appropriate
9 basis for the Court to reject the plan, even though the OCC
10 did not first make a separate motion for substantive
11 consolidation in advance of confirmation.

12 Now, of course, we want to do what the Court
13 thinks we need to do and if the Court were to conclude that a
14 motion or some other kind of procedural step is required for
15 the OCC to raise arguments of that kind, we want to make sure
16 those steps get taken and they get taken on a timely basis.
17 So, again, that's really why we filed our statement.

18 Now, since filing the statement, the debtors
19 reached out to us and, based on conversations that we have
20 had with them, one on July 21st and again yesterday, we
21 understand that the OCC and the debtors are now in agreement
22 on those procedural issues. And this is our specific
23 understanding of the agreement. We understand the debtors
24 agree that substantive consolidation and theories like alter
25 ego, veil piercing, and agency can appropriately be raised as

1 objections to the plan at confirmation without the need for
2 any separate motion practice or other procedural steps by the
3 OCC as a predicate to asserting those arguments.

4 For its part, provided that they can be raised and
5 adjudicated on the merits as appropriate plan objections at
6 confirmation, the OCC will not seek to have claims or
7 arguments of that kind determined prior to the confirmation
8 hearing in these cases.

9 Now, to be crystal clear and to perhaps state the
10 obvious, the debtors are not conceding that substantive
11 consolidation or alter ego or agency or doctrines that, if
12 asserted by the OCC, should be applied in these cases.
13 Presumably, if we raise those kinds of arguments, they're
14 going to say just the opposite that those doctrines do not
15 apply. But what we do understand the debtors to be agreeing
16 to is that the OCC can appropriately raise those kinds of
17 arguments as appropriate objections to the debtors' proposed
18 plan and, if those kinds of arguments are raised by the OCC
19 in connection with objecting to the plan, they must be
20 resolved on the merits before the plan can be confirmed one
21 way or the other, and that the Court may rely on those kinds
22 of doctrines, if raised and proven, as bases potentially for
23 denying plan confirmation, again, even though the OCC didn't
24 first raise the doctrines by motion.

25 So that's the understanding, our understanding of

1 the agreement. We are still hoping, Your Honor, to get the
2 Court's guidance because, of course, ultimately, it's going
3 to be up to Your Honor regardless of what the parties agree.
4 I will say, to be clear, if the Court prefers the OCC to
5 proceed in some other way, if the Court would like the OCC to
6 work with the debtors to come up with a written stipulation
7 for presentation to Your Honor to be so ordered, we would be
8 happy to do that.

9 The one thing that the OCC wants to avoid is to
10 find itself in some kind of procedural "gotcha" situation.
11 And so we would be very grateful for any guidance that the
12 Court might be willing to provide, so we can hopefully avoid
13 such a situation.

14 Thank you, Your Honor.

15 THE COURT: Thank you, Mr. Hurley.

16 Well, I can't say off the top of my head whether
17 or not it's required to file a motion for substantive
18 consolidation rather than just including -- I assume you
19 would include it within your objection to confirmation, which
20 in effect is the motion -- is a motion, you -- or response to
21 a motion, I guess. So you're objecting to plan confirmation
22 because the debtor should be substantively consolidated and I
23 think that is sufficient. I don't think you need to file a
24 separate motion at this time, I don't think there's anything
25 in the rules or the law that requires you to file a separate

1 motion for substantive consolidation. You might need to file
2 one for standing to bring a substantive consolidation motion,
3 but if you are bringing that motion in connection with
4 objection to confirmation, I think that is fine. But if the
5 parties want to make certain there's no -- nobody tries to
6 raise later on the gotcha, you didn't file a motion, I'm
7 happy to enter whatever stipulation the parties wish to enter
8 into.

9 MR. HURLEY: Thank you, Your Honor.

10 THE COURT: Mr. Freimuth?

11 MR. FREIMUTH: Good afternoon, Your Honor. This
12 is Matthew Freimuth from Willkie Farr on behalf of attestor
13 and Humana. Can you hear me okay?

14 THE COURT: I can. Thank you.

15 MR. FREIMUTH: Fundamentally, what we have now
16 after the filing of the preliminary objection by the debtors
17 is I believe a dispute about timing, whether our motion for
18 substantive consolidation should be heard in advance of
19 confirmation, as it's been noticed, or at or in connection
20 with confirmation.

21 Our view, Your Honor, is that we filed the motion
22 seeking substantive consolidation of the debtors' specialty
23 brands business and the Acthar entities on June 18th and
24 noticed it for a hearing more than two months later. There
25 was nothing improper about the filing of the motion, the

1 cases are clear that creditors have standing to pursue
2 substantive consolidation. The debtors cite no case finding
3 that a creditor needs to seek derivative standing to bring a
4 sub-con motion. And the cases are clear that substantive
5 consolidation can be sought by motion and that no adversary
6 proceeding is required.

7 The filing of the motion and the timing for the
8 hearing that we've set provide all parties in interest an
9 opportunity to be heard on our request and, consistent with
10 the dates in the confirmation discovery protocol, we've been
11 pressing for discovery relevant to the sub-con motion, and I
12 want to circle back to that. There have been some disputes
13 that will likely require the Court's attention, but documents
14 have been produced, depositions have been requested, they're
15 in the process of being scheduled and noticed. And so the
16 discovery needed and being sought coincides with and complies
17 with the discovery provisions of the confirmation protocol
18 and that fact discovery should be done in advance of August
19 25th when the motion is currently noticed.

20 It's not true, from our perspective, that hearing
21 the motion before confirmation is going to create some sort
22 of significant additional burden, the work is already
23 underway. We think there's great benefit in getting to the
24 merits of the sub-con issue promptly.

25 Mr. Harris in his remarks earlier today suggested

1 that we were engaging in an effort to slow these proceedings
2 now, we're not. We want this issue heard and resolved
3 promptly, Your Honor. He also alluded to the need to bring
4 clarity to the debtors and the various constituencies about
5 certain issues before confirmation, we think this is one.

6 So with that said, Your Honor, we think that it
7 would be perfectly appropriate and efficient for this Court
8 to hear the sub-con motion that we filed in advance of
9 confirmation on the date we noticed of August 25th.

10 I did allude, Your Honor, to one issue with
11 respect to certain discovery disputes. Whether you'd like me
12 to sort of address that now or later, the mere point I want
13 to make is we do have some disputes with respect to documents
14 that we're seeking in connection with sub-con and, frankly,
15 they cut across other confirmation and estimation issues as
16 well. I understand the process is to request a conference
17 with Your Honor. We would with respect to those issues, Your
18 Honor, like to file a short letter early next week, perhaps
19 by close of business Monday, teeing up the issues that exist
20 today. We've heard the Court loud and clear that, to the
21 extent that there are discovery disputes and issues that need
22 the Court's attention, it's on us to file the motion to
23 compel. So we would like to proceed on that basis.

24 THE COURT: All right. Well, let me hear -- Mr.
25 Simon, what's the debtors' view?

1 MR. SIMON: Well, Your Honor, I don't have -- I
2 defer to Mr. Harris or my litigators on the discovery
3 disputes, but I kind of do go back to the idea of you can't
4 just say discovery is underway and so we can have a hearing
5 on the 25th because, again, all of the confirmation protocol
6 dates and deadlines were with a September 21st hearing in
7 mind. And it's no surprise that our plan doesn't have
8 substantive consolidation, it never has. So the original
9 plan, I believe, was filed in April, and there was various
10 updates to the documents and the order was approving the DS
11 and the plan for solicitation I believe was June 25th,
12 roughly at that time frame.

13 So this issue about not seeking substantive
14 consolidation has always been our position. I mean, we teed
15 up that issue. So the idea that we could have a plan on file
16 that's always been no sub-con and then a creditor can say,
17 well, let's decide sub-con early, that's literally what we
18 have scheduled for hearing on the 21st. So, again, like it's
19 not just enough to say, well, discovery is underway; that's
20 true, but it won't be done. That's the point is we need this
21 time frame to have these issues decided together because, if
22 anything is relevant to sub-con or not relevant to sub-con,
23 it's going to impact other issues. Best interests and unfair
24 discrimination come right to mind.

25 So if someone wants to depose a witness about an

1 intercompany agreement, assets moved from A to be, that's
2 going to be relevant for sub-con. It's also going to be
3 relevant for best interests and unfair discrimination
4 because, if those intercompany agreements are properly
5 documented and formalities are fulfilled, that negates sub-
6 con by definition and now people have the facts about best
7 interests and unfair discrimination, because if they sit at
8 certain boxes where the notes are and not other claims, that
9 is unbelievably relevant to best interests and unfair
10 discrimination. So everyone is going to have to show up and
11 argue every issue about where assets sit.

12 So it's not just this isolated issue that can be
13 decided on its own on the 25th.

14 THE COURT: Mr. Freimuth, I was taken by one thing
15 that you said that the discovery you're seeking does overlap
16 other issues that relate to confirmation. So I guess I'm
17 struggling with what's -- why not wait until we get to
18 confirmation? We could have -- we could start off the
19 confirmation hearing with the question of whether or not
20 substantive consolidation is appropriate and then I can
21 perhaps make a ruling on that before we go further into the
22 confirmation hearing, which would resolve the issue one way
23 or the other. Either the plan is not going to get confirmed
24 or I'll overrule it and we go on with the other issues.

25 MR. FREIMUTH: All I meant to suggest by that

1 comment, Your Honor, is some of the specific categories of
2 documents and data that we're seeking where we have disputes
3 could very well be relevant to issues related to substantive
4 consolidation. They may come up in the context of estimation
5 of our prepetition claim or they -- you know, they may be
6 relevant to various confirmation issues. So I was speaking
7 specifically with respect to -- one of the categories, for
8 example, is subsidiary minutes of the various boards of
9 directors.

10 So, to your point, we think that getting clarity
11 on these issues prior to confirmation makes good sense, it's
12 an efficient way to resolve the question up front, so that
13 we're not headed to a confirmation hearing months later with
14 questions about whether or not the Acthar entities or the
15 specialty brands entities should be consolidated or not.

16 And in response to the point about whether
17 discovery is ongoing, the fact of the matter is the fact
18 depositions and the witnesses that are going to be testifying
19 about these issues, we understand from the debtor they're
20 going to be made available for deposition in the first two
21 weeks of August. So the record ought to be developed and
22 ready to present to Your Honor in advance of confirmation.

23 MR. SIMON: Your Honor, it's Keith Simon. Could I
24 say one thing, though, just to put this in context, which is
25 if you scheduled a hearing for the 25th, I'm not sure if that

1 means that the OCC has to say we agree with sub-con right
2 now, like are we going to do this hearing twice?

3 So, again, like I just don't -- I feel like it's
4 going to be an inefficient use of this Court's time because
5 that means that everyone will have to argue it. Otherwise,
6 if Humana argues it and you agree with us, then does the OCC
7 get bound by that as law of the case because you found that
8 formalities were fulfilled and properly followed, but because
9 Akin Gump didn't raise it they are now bound by that? It
10 just -- I don't see how it practically works to have a
11 hearing on this issue in advance of confirmation when you
12 could say those exact same arguments about every confirmation
13 requirement. This plan can't go forward if you think it
14 violates the best interests test --

15 THE COURT: Well, I --

16 MR. SIMON: -- that's just one example.

17 THE COURT: Well, I think that's a good point. I
18 mean, I can't -- if we go forward on a separate motion on
19 sub-con, anybody who has a sub-con objection is going to have
20 to participate in that. And because the discovery issues
21 overlap one another, it just doesn't -- it doesn't seem to be
22 efficient -- the efficiencies actually go the other way, I
23 think. I think it's less efficient to go forward on August
24 25th with a sub-con, a separate sub-con hearing that's going
25 to require everybody's participation just weeks before we get

1 to the confirmation hearing. It is a confirmation-type
2 issue.

3 So I just think the efficiencies here would be
4 let's do this on the first day of the confirmation hearing.
5 We'll hear the motion for sub-con on day one of the
6 confirmation hearing, and I can rule on that and then we can
7 move into other issues. And maybe there's other issues that
8 will come up along the way that we need to -- we could do
9 this, you know, rule on them as we go rather than doing a
10 week-long hearing and then have me try to write an 80-page
11 opinion about all these different issues.

12 I'll open it -- I mean, what do people think about
13 that? Mr. Freimuth, because it's your motion, so --

14 MR. FREIMUTH: Yeah, Your Honor, that would be
15 acceptable to us to have that motion heard at the first day
16 of confirmation, as you've just described.

17 THE COURT: All right. That allows us to get
18 through all the discovery. There may be overlapping
19 discovery issues, everybody is going to want to participate
20 in those depositions, so I think that makes sense to do it
21 that way.

22 Mr. Simon, does that cause any concerns on your
23 part?

24 MR. SIMON: Your Honor, obviously, ultimately, if
25 that's what Your Honor prefers, we will of course go with

1 that. But, again, you know, our initial idea was that our
2 case in chief would moot this issue, but if it's Humana's
3 independent motion, then obviously it's their burden to prove
4 sub-con. It's their motion and, if they're the proponent,
5 they're going to have to satisfy it by Owens Corning and it's
6 their burden. So, if they want to have it heard first
7 outside of plan confirmation the day of, it's their burden.
8 I just want to make sure that that's crystal clear.

9 THE COURT: It is. It is your burden, Mr.
10 Freimuth, you're going to have to meet the requirements of
11 Corning to show sub-con.

12 MR. FREIMUTH: We understand, Your Honor.

13 THE COURT: All right. Okay.

14 MR. FREIMUTH: Apologies, Your Honor. There was
15 the issue that I did raise with respect to some discovery
16 disputes --

17 THE COURT: Yes.

18 MR. FREIMUTH: -- that have arisen that, frankly,
19 have ripened up just, I would say, within the last 12 hours
20 or so. So it's a few categories of documents, one relates to
21 a request that we have outstanding for minutes of subsidiary
22 boards, another relates to some outstanding data requests we
23 have. My proposal, Your Honor, is that we just set a
24 schedule today where we could file a short letter with the
25 Court indicating what the disputes are and indicating the

1 relief we're requesting. We could be prepared to do that
2 very early in the week next week.

3 THE COURT: Well, the one problem with very early
4 in the week next is I'm going to be on vacation next week.
5 I'm not going to disappoint my granddaughter. So I'm not
6 going to do any work while I'm vacation. So I wouldn't be
7 able to address it until the week after next.

8 Have the parties met and conferred on these issues
9 and you're at an impasse, is that where you are at this
10 point?

11 MR. FREIMUTH: We have met and conferred, Your
12 Honor, I do believe we're at an impasse with respect to at
13 least the request for subsidiary board minutes.

14 THE COURT: Well, that sounds like a pretty
15 discrete issue. Why don't we -- go ahead and file it next
16 week. I'll try to get to it as soon as possible. It may not
17 be until I get back on August 2nd, but if the parties -- if
18 you want to file a -- if it's just that one discrete issue,
19 that sounds like it could be done in just a few pages, a few-
20 page letter.

21 MR. FREIMUTH: Yeah. And to be clear, Your Honor,
22 the other issue relates to data that we're requesting that we
23 believe supports the liquidation analysis and valuation that
24 underlies the debtor's disclosure statement. It is also a
25 very discrete issue, so I think we could present both to you

1 within two pages.

2 THE COURT: Okay. Then why don't you go ahead and
3 file yours Monday or Tuesday, whenever you are ready. I'll
4 give the debtors an opportunity to reply by -- you know, I'll
5 give you two days to reply, Mr. Simon or Mr. Harris, whoever
6 is going to reply, and then we'll take it from there.

7 MR. FREIMUTH: Okay.

8 THE COURT: And I may just look at them and pass
9 on to my courtroom deputy what my ruling is and he can let
10 you know -- or let you know at least what I'm thinking.
11 Maybe that will help move things along.

12 MR. FREIMUTH: Okay. We appreciate that, Your
13 Honor.

14 THE COURT: All right. Okay.

15 Mr. Hurley, you raised your hand.

16 MR. HURLEY: Thank you, Your Honor. I just wanted
17 to hopefully make something clear in terms of our timing. So
18 it sounds like what we're contemplating is that the OCC will
19 be able to make whatever arguments it has on sub-con or
20 similar, if any, in its objection, and then also will have an
21 opportunity to be heard on those issues at the outset of the
22 hearing, and I guess alongside attestor or other parties that
23 are making similar arguments. Do I have that right?

24 THE COURT: Yes, absolutely. Yes.

25 MR. HURLEY: Okay. And it may make sense, as you

1 suggested, Your Honor, for us to try and get that
2 memorialized in a stipulation, and I'll reach out separately
3 to Mr. Simon on that.

4 THE COURT: Okay.

5 MR. HURLEY: Thank you.

6 THE COURT: All right.

7 MR. SIMON: And, Your Honor, just procedurally,
8 Mr. Hurley reminded me of a very good point. I mean, the
9 hearing was originally scheduled for August 25th with an
10 objection deadline of August 6th. So because it's going to
11 be heard at confirmation, when I assumed our response would
12 be part of our confirmation brief, but I wanted to make sure
13 that was what Your Honor was thinking as well. I just want
14 to know when our objection deadline is -- I know when the
15 hearing is, but I want to know when we have to respond.

16 THE COURT: Well, if you make it a part of your
17 confirmation brief, then Mr. Freimuth isn't going to get a
18 reply.

19 MR. SIMON: Okay.

20 THE COURT: So I think we're going to have to set
21 that as a separate schedule.

22 MR. SIMON: Okay.

23 THE COURT: So -- just so that he has the
24 opportunity to file his reply. But I'll let the parties work
25 that out in terms of timing.

1 MR. SIMON: We'll talk. Maybe the idea will be
2 they have their plan objections due on September 3rd, maybe
3 ours is due September 3rd for this, and then they reply at
4 the same time as our confirmation brief, maybe something like
5 that. But we'll talk and that's fine.

6 THE COURT: Yeah. Hopefully, you can get that
7 worked out. I think that should be able to be resolved.

8 MR. SIMON: Okay.

9 THE COURT: All right. Anything else for today?

10 MR. MERCHANT: Your Honor, the only other thing I
11 failed -- I neglected to mention that is on the agenda is the
12 attestor and Humana asked that there be a status conference
13 on their estimation motion, and that is the one remaining
14 item on today's hearing agenda.

15 THE COURT: All right. Let me hear from attestor.

16 MR. FREIMUTH: Sure, Your Honor. You'll recall
17 that when we had our estimation motion heard on the 7th we
18 asked for a status conference to be set for the day on which
19 Your Honor was going to hear argument on the unsubstantiated
20 claims objection. Just by way of update, since June 7th, on
21 June 21st, the debtors advised us that they would engage with
22 us on discovery on the underlying merits of the claims in
23 anticipation that estimation may be necessary, and so that
24 process has been underway. Arnold & Porter, who represents
25 the debtors in the underlying Humana case, has appeared,

1 we've engaged in meet-and-confers.

2 Practically, what that has meant is that since
3 June 21st, when the debtors agreed to begin providing us
4 merits discovery, they provided us with 1.8 million
5 documents, some of which has taken weeks to load onto our
6 review platform, but we are moving through that material as
7 quickly as we possibly can.

8 On Tuesday of this week, the debtors advised us
9 that they would anticipate that, to the extent that we have
10 questions of their witnesses related to the merits of either
11 the prepetition claims or the admin claims, that we would be
12 prepared to ask those witnesses questions during the first
13 two weeks of August. Obviously, with respect to the document
14 flow, we have some serious concerns about that schedule.
15 Obviously, whatever the debtors propose with respect to a
16 schedule we'll consider, but there may well be issues to the
17 extent that depositions get scheduled and documents related
18 to the merits of either the prepetition claim or the admin
19 claim remain outstanding.

20 So we're working through those issues. There's
21 nothing, I think, ripe to present to Your Honor today, but I
22 just wanted to alert you that that process is ongoing and we
23 are getting quite a volume of documents. We've gotten
24 commitments from the debtors to produce additional documents
25 with no clear indication yet as to exactly when those are

1 coming. So we just wanted to alert Your Honor that that
2 process is underway.

3 THE COURT: All right. Thank you. That's the
4 problem with discovery is sometimes you get what you ask for.
5 You've got too many documents to review.

6 Mr. Harris?

7 MR. HARRIS: And, Your Honor, just to follow up
8 and clarify. Mr. Freimuth is right, we have been going
9 forward with full discovery on the merits of the underlying
10 claims against PLC and ARD to be prepared if we decided that
11 estimation is needed, all that was awaiting a decision on our
12 omnibus objection. So we will take this time and think about
13 over the weekend whether we believe estimation is needed.
14 You know, likely, I think we may decide it is not, and we can
15 talk again and we're happy to talk again with attestor about
16 our views on that, you know, next week.

17 I just didn't want to leave hanging out there that
18 there was any decision made that in fact now estimation is
19 needed, it may well be the debtors' view that it is not.
20 But, as he said, we have been producing discovery regardless
21 so the parties would be prepared in the event that we do need
22 to estimate.

23 THE COURT: Thank you, Mr. Harris.

24 All right, anything else for today, Mr. Merchant?

25 MR. MERCHANT: I believe that's all for today. I

1 thank the Court for its time and have a great vacation, Your
2 Honor.

3 THE COURT: All right. Thank you all very much.
4 Have a good weekend, and I know my week will be better than
5 yours.

6 (Laughter)

7 THE COURT: All right. We're adjourned.

8 COUNSEL: Thank you, Your Honor.

9 THE COURT: Thank you.

10 (Proceedings concluded at 3:52 p.m.)
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CERTIFICATE

We certify that the foregoing is a correct transcript
from the electronic sound recording of the proceedings in the
above-entitled matter.

/s/Mary Zajackowski June 24, 2021
Mary Zajackowski, CET**D-531

/s/William J. Garling June 24, 2021
William J. Garling, CE/T 543

/s/ Tracey J. Williams June 24, 2021
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LEAD, SealedDoc(s), MEGA, STANDOrder, CLMSAGNT, APPEAL

**U.S. Bankruptcy Court
District of Delaware (Delaware)
Bankruptcy Petition #: 20-12522-JTD**

Assigned to: John T. Dorsey
Chapter 11
Voluntary
Asset

Date filed: 10/12/2020
341 meeting: 02/12/2021
Deadline for filing claims: 02/16/2021

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07/23/2021	3405 (6 pgs)	Minute Entry Re: 3389 ; Telephonic Hearing Held Re: 2165 , 2578 , 3228 ; debtors' first omnibus objection to unsubstantiated claims (2165) is SUSTAINED (***The record for this hearing is SO ORDERED***); order to follow; motions to seal (2578 and 3228) are GRANTED; orders to be uploaded for signing; Appearances: (See Attached Registration Sheets) (RC) (Entered: 07/23/2021)

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CERTIFICATE OF SERVICE

I, Matthew O. Talmo, hereby certify that I am not less than 18 years of age and that service of the foregoing was caused to be made on July 28, 2021 via CM/ECF upon those parties registered to receive such electronic notifications and via email upon counsel to Mallinckrodt PLC and its affiliated debtors.

Dated: July 28, 2021

/s/ Matthew O. Talmo
Matthew O. Talmo (Bar No. 6333)

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THE UNITED STATES
DEPARTMENT OF JUSTICE

CREDITOR'S CLAIMS IN BANKRUPTCY PROCEEDINGS -- THE DEBTOR-CREDITOR RELATIONSHIP IN BANKRUPTCY -- ALLOWANCE AND PAYMENT OF CLAIMS

B. Asserting Claims To The Bankruptcy Estate

1. Whether to File a Claim

a. Necessity of filing

(1) General rule: filing is required. The only claims allowed to share in the bankruptcy estate are those for which proofs have been filed. *Wilson v. Allegheny Int'l, Inc.*, 134 B.R. 282 (N.D. Ill. 1991). When in doubt, file proof of claim.

(2) Exceptions to filing requirement

(a) Lack of knowledge

(i) Of bankruptcy case

See *In re Global Precious Metals, Inc.*, 143 B.R. 204 (Bankr. N.D. Ill. 1992). Held, lack of notice does not authorize court to extend bar date; however, Code protects creditors, namely, § 523(a)(3) (lack of creditor notice renders nondischargeable claim against individual debtor); § 726(a)(2)(C) (claim not subordinated if filed late due to lack of notice); § 501(c) (debtor or trustee may file proof of claim if creditor does not file timely).

Due process should protect creditor where these provisions fail to do so. See *Broomall Indus. v. Data Design Logic Sys.*, 786 F.2d 401 (Fed. Cir. 1986); *Reliable Elec. Co. v. Olson Constr. Co.*, 726 F.2d 620 (10th Cir. 1984); *United States v. Cole (In re Cole)*, 146 B.R. 837 (D. Colo. 1992). **Unknown** creditors' claims will be discharged if there is sufficient notification publication notice, usually through national newspapers. However, due process requires that **known** creditors receive formal actual notice of a bankruptcy case before the discharge affects their claims. A known creditor is one whose identity is either known or reasonably ascertainable by the debtor; a creditor's identity is reasonably ascertainable if that creditor can be identified through reasonably diligent efforts. Ed. Note: This protection from discharge applies equally to the United States. In the case of governmental entities, "adequate notice" must satisfy requirement of "fundamental fairness" rather than due process. However, this standard still requires that if the federal agency was a known creditor it must have received actual formal notice of a bankruptcy case before its claims are discharged. That the federal agency knew through informal means, i.e., word of mouth, that the debtor was in bankruptcy is not sufficient. If the agency was not sent the formal notices required by the Code we should be arguing that its claim is not discharged.

Priority tax claim, filed late because IRS was not notified of bankruptcy case or bar date, should be treated same as if filed timely. *United States v. Cardinal Mine Supply, Inc.*, 916 F.2d 1087 (6th Cir. 1990); see also *United States v. Ulrich (In re Mantz)*, 151 B.R. 928 (Bankr. 9th Cir. 1993) (same fact pattern, denied IRS priority but allowed general unsecured claim), *rev'd*, No. 93-15985, 1994 WL 447271 (9th Cir. Aug. 19, 1994); *IRS v. Century Boat Co. (In re Century Boat Co.)*, 986 F.2d 154, 156-57 (6th Cir. 1993) (*Cardinal Mine* does not save every priority claim); *United States v. Vecchio*, 147 B.R. 303 (E.D.N.Y. 1992) (held *Cardinal Mine* inapplicable where IRS given notice in time to file claim), *rev'd*, 20 F.3d 555 (2d Cir. 1994).

[Note: Section 213(b) of the Bankruptcy Reform Act of 1994 amends Code § 726(a)(1) to preserve the order of distribution for priority claims "tardily filed before the date on which the trustee commences distribution under this title."]

(ii) Of existence of claim

"In most cases, we anticipate that the government will not possess sufficient knowledge to assert a potential claim until completion of a post-award audit." *In re Remington Rand Corp.*, 836 F.2d at 833 n.7.

(b) Debtor's schedules -- chapters 9, 11 [§§ 925, 1111(a)] -- list claim as undisputed, fixed, liquidated. Rule 3003(b)(1) (filing not required); *see also* Rule 1019 (effect of conversion of case to chapter 7).

(c) "No asset" chapter 7. Rule 2002(e), 3002(c)(5). In some jurisdictions, clerk will not accept proof of claim in "no asset" case.

b. Reasons for asserting a claim

A claim exists whether or not a proof of claim is filed. Filing is required only to permit creditor's participation in the case. *Grynberg v. United States (In re Grynberg)*, 986 F.2d 367, 371 (10th Cir. 1993).

(1) Involuntary petitions [§ 303]

(2) Administration of estate -- creditors' committees. §§ 1102, 1103. However, under current law, government eligibility for committee membership is limited.

(3) Objection to discharge [§ 727(e)]

(4) Voting on [§ 1126] or objecting to plan [§§ 1225, 1325]

(5) Participation in distribution of estate property through liquidation dividends or plan payments [§§ 726, 1123, 1222, 1322]

c. Considerations in deciding whether to file claim

(1) Sovereign immunity

Filing proof of claim waives sovereign immunity permitting bankruptcy court to decide counterclaims by estate against government. *See* § 106(b).

(2) Jury trial

Filing proof of claim waives right to jury trial on counterclaims. *See Langenkamp v. Culp*, 498 U.S. 42 (1990) (*per curiam*).

(3) Nondischargeable claims

Some categories require creditor to take affirmative step of requesting that debt be excepted from discharge. *See* § 523(c)(1).

(4) Secured claims (including setoff)

Unavoided liens survive bankruptcy, *see* § 506(d)(2); *In re Tarnow*, 749 F.2d 464 (7th Cir. 1984), but circumstances may demand action by secured creditor to protect lien. *See In re Newport Offshore, Ltd.*, 78 B.R. 383 (Bankr. D.R.I. 1987) (denying setoff right).

2. When to File a Claim in a Bankruptcy Case

a. "Bar date." The bar date establishes the date by which claims must be filed against the estate.

A bar order serves the important purpose of enabling the parties to a bankruptcy case to identify with reasonable promptness the identity of those making claims against the bankruptcy estate and the general amount of the claims, a necessary step in achieving the goal of successful reorganization. ... Thus, a bar order does not "function merely as a procedural gauntlet," ... but as an integral part of the reorganization process.

First Fidelity Bank, N.A. v. Hooker Inves., Inc. (In re Hooker Inves.), 937 F.2d 833, 840 (2d Cir. 1991). The bar date is akin to a statute of limitations and must be strictly observed. *In re Keene Corp.*, 188 B.R. 903, 907 (Bankr. S.D.N.Y.

1995).

(1) Fixed by rule in chapters 7, 12 and 13 with some exceptions, e.g., upon timely request, court may extend deadline for U.S. to file. See Rule 3002(c). **Note: as a rule, bankruptcy deadlines are relatively short. Time is of the essence.**

(2) Set by court in chapters 9 and 11 [Rule 3003(c)(3)]

(3) **"A claim of a governmental unit shall be timely filed if it is filed before 180 days after the date of the order for relief or such later time as the Federal Rules of Bankruptcy Procedure may provide."**

(4) Rejected executory contracts and unexpired leases -- court sets date [Rule 3002(c)(4)]

(5) Postpetition claims. § 503. Note: a motion for an administrative expense shall be made upon application and notice pursuant to § 503 and not by proof of claim. *Security Ins. Corp. of Hartford v. First Century Corp. (In re First Century Corp.)*, 166 B.R. 47 (Bankr. M.D. Pa. 1994). Section 213(c) of the Bankruptcy Reform Act of 1994 amends Code § 503 to provide that the court may permit tardy filing of an administrative expense claim for cause.

(6) Effect of conversion of case. Rule 1019; see *United States v. Ginley (In re Johnson)*, 901 F.2d 513 (6th Cir. 1990) (upon conversion of case from ch. 11 to ch. 7, IRS was required to comply with the bar date set for claims arising in the superseded ch. 11 case with respect to taxes incurred postpetition but preconversion).

(7) Amendment of claims. Should be freely permitted, and amendment **not creating new or additional claim** may be filed after expiration of normal time limits. See *Woburn Assocs. v. Kahn (In re Hemingway Transp., Inc.)*, 954 F.2d 1 (1st Cir. 1992); *In re Unroe*, 937 F.2d 346 (7th Cir. 1991); *In re Donovan Wire & Iron Co.*, 822 F.2d 38 (8th Cir. 1987); *In re International Horizons, Inc.*, 751 F.2d 1213 (11th Cir. 1985); *In re Dietz*, 136 B.R. 459 (Bankr. E.D. Mich. 1992); *In re Walls & All, Inc.*, 127 B.R. 115 (W.D. Pa. 1991). "The crucial inquiry is whether the opposing party would be unduly prejudiced by the amendment." *Roberts Farms Inc. v. Bultman (In re Roberts Farms Inc.)*, 980 F.2d 1248, 1251 (9th Cir. 1992); see also *Matter of Alliance Operating Corp.*, 60 F.3d 1174 (5th Cir. 1995) (Changing the type of claim from unsecured to priority sets forth a new claim and is not permitted through amendment of an existing proof of claim.); *In re Brown*, 159 B.R. 710 (Bankr. D.N.J. 1993).

b. Missed deadlines

(1) Avoiding default

(a) First, look for an exception to the filing requirement, e.g., failure to provide adequate notice. See *City of New York v. New York, New Haven & Hartford R.R. Co.*, 344 U.S. 293 (1953) (where creditor was not given reasonable notice of bar date for filing proof of claim, creditor was not barred from asserting claim post-confirmation); *In re Spring Valley Farms, Inc.*, 863 F.2d 832 (11th Cir. 1989); *Broomall Indus. v. Data Design Logic Sys.*, 786 F.2d 401, 405 (Fed. Cir. 1986) (even if creditor had actual notice of bankruptcy proceeding, "that fact would not have obviated the necessity for the service of formal notice" on creditor); *Reliable Elec. Co., Inc. v. Olson Constr. Co.*, 726 F.2d 620, 622-23 (10th Cir. 1984); *In re Intaco Puerto Rico, Inc.*, 494 F.2d 94, 99 (1st Cir. 1974); *In re Harbor Tank Storage Co., Inc.*, 385 F.2d 111, 115 (3d Cir. 1967); *In re Arlington Heights Congregate Housing Partnership*, 189 BR 187 (Bankr. S.D. Ind. 1995) (without formal notice, actual knowledge of the bankruptcy case will not suffice and a known creditor's claim must be allowed even if late filed); *In re Interstate Cigar Co.*, 150 B.R. 305, 309 (Bankr. E.D.N.Y. 1993).

(b) Informal proof of claim

"A failure to comply with the [Bankruptcy Codes's] claim filing requirements ... is not necessarily the death knell for a misguided or inattentive creditor. The bankruptcy court may allow a Chapter 11 claim ... when a disallowance of the

claim will produce an unfair result through no fault of the creditor. Allowance of such a claim, upon the manifestation of an intent to hold the estate liable on the debt, has come to be known as an informal proof of claim. ... The [informal proof of] claim must be in writing; there must be a demand by the creditor on the estate; it must evidence an intent to hold the debtor liable; the claim must be filed with the bankruptcy court; and allowance of the claim must be equitable under the facts of the case." *Matter of Plunkett*, 191 B.R. 768, 774 (Bankr. E.D. Wis. 1995); *accord Clark v. Valley Fed. Savs. and Loan Ass'n (In re Reliance Equities, Inc.)*, 966 F.2d 1338, 1345 (10th Cir. 1992). Whether the writing must be filed with the court is subject to controversy. *Compare In re County of Orange*, 191 B.R. 1005, 1022 (Bankr. C.D. Cal. 1996) (Informal letter to the debtor/trustee was sufficient for informal proof of claim) and *In re Dauer*, 165 B.R. 146, 147 (Bankr. D.N.J. 1994) ("To constitute an informal proof of claim there must be a writing which makes a demand on the estate and/or expresses an intent to hold the estate liable for the debt.") with *In re Cole*, 189 B.R. 40, 51 (Bankr. S.D.N.Y. 1995) (An informal proof of claim requires a "timely written assertion or pleading," which "appris[e] the court of the existence, nature, and amount of the claims") (emphasis added).

(c) Excusable neglect

Courts are permitted to accept late filings caused by inadvertence, mistake, or carelessness, not just by intervening circumstances beyond the party's control. FRBP 9006(b)(1); *Pioneer Inv. Servs. Co. v. Brunswick Assocs. L.P.*, 113 S. Ct. 1489 (1993). In making this equitable determination, courts should consider (1) the danger of prejudice to the debtor, (2) the length of the delay and its potential impact on judicial proceedings, (3) the reason for the delay, including whether it was within the reasonable control of the movant, and (4) whether the movant acted in good faith. *Id.* at 1498; *Agribank v. Green*, 188 B.R. 982, 989 (C.D. Ill. 1995) (Intentional failure to file proof of claim timely so that its claim would be definitively stated and would not have to be amended is not excusable neglect.).

(2) Consequences of missing filing deadline

(a) Secured claims: "Ordinarily, liens and other secured interests survive bankruptcy." *Farrey v. Sanderfoot*, 500 U.S. 291, 297 (1991). "Because an unchallenged lien survives the discharge of the debtor in bankruptcy, a lienholder need not file a proof of claim under section 501." *Folendore v. SBA (In re Folendore)*, 862 F.2d 1537, 1539 (11th Cir. 1989). However, creditor loses right to proceed *in personam* against the debtor. *See Johnson v. Home State Bank*, 501 U.S. at 84.

(b) Setoff: Nothing in § 553 requires that a right of setoff be asserted in a proof of claim to be preserved. To the contrary, § 553 expressly provides that nothing in the Code affects a creditor's right to setoff unless explicitly stated in § 553, which makes no mention of proofs of claim. Despite this, whether failing to file a proof of claim or failure to assert a right of setoff in a proof of claim may waive that right is subject to controversy. *Compare In re Davidovich*, 901 F.2d 1533, 1539 (10th Cir. 1990) (proof of claim not prerequisite to retention of setoff right); *Willcox v. Goess*, 92 F.2d 8, 16 (2d Cir. 1937), *cert. denied*, 303 U.S. 647 (1938) (setoff under Bankruptcy Act allowable on provable claim even if no proof made and bar date passed); *Bloor v. Shapiro*, 32 B.R. 993, 1002 (S.D.N.Y. 1983) (setoff permissible even in absence of timely filed proof of claim); *In re Aquasport, Inc.*, 155 B.R. 245, 247 (S.D. Fla. 1992), *aff'd*, 985 F.2d 579 (11th Cir. 1993); *In re Concept Clubs, Inc.*, 154 B.R. 581, 589 (D. Utah 1993); *Stratton v. Equitable Bank*, 104 B.R. 713, 735 (D. Md. 1989); *In re Calderone*, 166 B.R. 825, 830 (Bankr. W.D. Pa. 1994); *In re Selma Apparel Corp.*, 155 B.R. 241, 244 (Bankr. S.D. Ala. 1992); *In re Suncrete Corp.*, 100 B.R. 102, 104 (Bankr. M.D. Fla. 1989); *In re Denby Stores*, 86 B.R. 768, 777 (Bankr. S.D.N.Y. 1988); Lawrence P. King, 4 *Collier on Bankruptcy* ¶ 553.01[4], at 553-6 (15th ed. 1993) (all allowing setoff without filing proof of claim) and *In re Custom Ctr., Inc.*, 163 B.R. 309, 315-17 (Bankr. E.D. Tenn. 1994) (failure to assert setoff in original proof of claim does not waive right to setoff) with *In re Britton*, 83 B.R. 914, 919-921 (Bankr. E.D.N.C. 1988); *In re Butler*, 61 B.R. 790 (Bankr. S.D. Fla. 1986); and 4 *Collier on Bankruptcy* ¶ 553.07, at 553-43 (all asserting that failure to preserve setoff in proof of claim is waiver of that right). *See also In re Village Craftsman, Inc.*, 160 B.R. 740, 748 (Bankr. D.N.J. 1993) (setoff waived when creditor files unsecured proof of claim and does not object to unsecured treatment in plan of reorganization); *In re Apex Int'l Mgmt. Servs., Inc.*, 155 B.R. 591 (Bankr. M.D. Fla. 1993); *In re Sound Emporium*, 48 B.R. 1 (Bankr. W.D. Tex. 1984) (both holding that setoff permitted if failure to assert that right in proof was good faith mistake and led to no detrimental reliance by other parties).

(c) Unsecured claims:

Chapter 7: Section 726(a)(3) permits payment of claims filed late but only after payment in full of timely filed general unsecured claims. Decisions allowing late claims in chapter 7 cases include *In re Sea Air Shuttle Corp.*, 168 B.R. 501 (Bankr. D.P.R. 1994); *In re Brennan*, 167 B.R. 316 (Bankr. D. Mass. 1993); *In re Osman*, 164 B.R. 709 (Bankr. S.D. Ga. 1993); *In re Brenner*, 160 B.R. 302 (Bankr. E.D. Mich. 1993); *In re McLaughlin*, 157 B.R. 873 (Bankr. N.D. Iowa 1993); *In re Rago*, 149 B.R. 882 (Bankr. N.D. Ill. 1992); *In re Corporacion de Servicios Medico-Hospitalarios de Fajardo, Inc.*, 149 B.R. 746 (Bankr. D.P.R. 1993).

Chapter 13: Courts are split. *Compare In re Hausladen*, 146 B.R. 557 (Bankr. D. Minn. 1992) (Rule 3002 is inconsistent with the Code in that it requires disallowance of late-filed claims in chapter 13) *with In re Duarte*, 146 B.R. 958 (Bankr. W.D. Tex. 1992) (Rule 3002 bars late-filed claims unless one of the 6 exceptions is met or denial of due process can be demonstrated).

[Note: Section 213(a) of the Bankruptcy Reform Act of 1994 amends Code § 502(b) to disallow tardily filed claims except as provided in § 726(a)(1), (2), or (3) or the Bankruptcy Rules. The legislative history states that the amendment is designed to overrule *Hausladen* and its progeny. 103 Cong. Rec. H10768 (daily ed. Oct. 4, 1994).]

3. Filing the Claim

a. Proof of claim "shall be *executed* by the creditor or the creditor's authorized agent" Rule 3001(b) (emphasis added).

b. Filing on behalf of the government

(1) Filing proof of claim is analogous to filing a complaint in a civil action for purposes of litigation authority. Thus, DOJ or U.S. Attorney files the claim with the court. (Note: this is particularly important where multiple agencies are involved in the case and where preserving sovereign immunity is a primary consideration.)

(2) Creditor agency may file if agency has litigation authority or by arrangement with DOJ, e.g., IRS Special Procedures function for filing tax claims, or in emergency. *In re Schibilsky*, 185 B.R. 81 (Bankr. N.D. Ga. 1995) (IRS has properly delegated authority to file proofs of claim on behalf of United States.).

(3) Third parties may file. § 501(b), (c). However, third party does not waive sovereign immunity by filing claim on behalf of government. See legislative history of § 106. H.R. Rep. No. 95-595, 95th Cong., 1st Sess. 317 (1977); S. Rep. No. 95-989, 95th Cong., 2d Sess. 29-30 (1978).

c. What to file

(1) Proof of claim. A "written statement" which "shall conform substantially to the appropriate Official Form." Rule 3001(a); see Official Form 10 (Rev. 6/91).

To preclude possible inadvertent waiver of rights, DOJ recommends that any government proof of claim contain a statement to the following effect:

This claim reflects the known liability of the debtor to this agency of the United States. The United States reserves the right to amend this claim to assert subsequently discovered liabilities. This agency holds subject to setoff against this claim a debt owed to the debtor of _____ (amount). The identification of any sums held subject to setoff is without prejudice to any other right under 11 U.S.C. § 553 to set off, against this claim, debts owed by this or any other Federal agency.

(2) Supporting documents. Rule 3001(c), (d). Copies of the documents evidencing the government's claim, including its lien position if applicable, should be attached with a certified statement of account showing the amount owing on the petition date.

(3) Internal documents: Claims Collection Litigation Report. See 4 C.F.R. § 105.2. Applicable to claims under Civil Division cognizance. See attachments to this outline regarding current Nationwide Central Intake Facility procedures applicable in bankruptcy cases. (Note: NCIF procedures and CCLR do not

apply to tax claims, which are filed by IRS, or to environmental claims, which as a general rule are forwarded by the agency directly to the Environment and Natural Resources Division for filing.)

C. Allowance and Payment of Claims

1. Allowability

a. Proof of claim is *prima facie* evidence of validity and amount of claim. Rule 3001(f). See § 502(a) (claim deemed allowed absent objection); *In re White*, 168 B.R. 825, 828-29 (Bankr. D. Conn. 1994).

b. Claims scheduled as undisputed, fixed, liquidated in chapters 9, 11 [Rule 3003]

c. Estimation of claims [§ 502(c)]

d. Temporary allowance to permit voting on plan where objection is pending [Rule 3018(a)]

2. Resolving Objections

a. A "party in interest" may object. § 502. This becomes a "contested matter." See Rule 9014. If the objection is joined with a demand for relief of the kind specified in Rule 7001, it becomes an adversary proceeding. Rule 3007. Once the objector produces some evidence (the mere filing of an objection is insufficient) disputing the validity of a claim, the burden shifts to the claimant. The claimant bears the ultimate burden of establishing a valid claim by a preponderance of the evidence. *In re South Motor Co.*, 161 B.R. 532, 547 (Bankr. S.D. Fla. 1993).

b. Objections to government claims. Differing views regarding extent of notice that must be given to United States. Compare *In re Morrell*, 69 B.R. 147 (N.D. Cal. 1986) (objection to IRS claim must be served upon Attorney General and U.S. Attorney in addition to the IRS because the U.S. is the actual claimant) with *In re Hejl*, 85 B.R. 399 (Bankr. W.D. Tex. 1988) (Rule 3007 does not require service upon U.S. Attorney where IRS claim is involved), *rev'd*, No. MO-88-CA-165 (W.D. Tex. Oct. 11, 1988). See generally *In re M & L Business Machine Co., Inc.*, 190 B.R. 111, 115-16 (D. Colo. 1995) ("In light of the comparatively lenient procedure in bankruptcy, persons effecting service must provide correct notice in accordance with the rules. Thus, strict compliance with Rule 7004 serves to protect due process rights as well as assure bankruptcy matters proceed expeditiously." (citations omitted)). Unless the plan expressly reserves the debtor's right to object to claims postconfirmation, there is "no place in the postconfirmation world" for objections to claims. The only means to challenge a claim postpetition is through a motion to reconsider under § 502(j). *Matter of Bernard*, 189 B.R. 1017, 1020 (Bankr. N.D. Ga. 1996) (Filing an objection 26 months after confirmation -- when the chapter 13 plan expressly required objections to be filed within 6 months of confirmation -- was "unreasonable and unjustifiable.").

c. Determining tax claims [§ 505]

d. Subordination [§ 510]

e. Reconsideration [§ 502(j); Rule 3008]

f. Appeal [Rules 8001-8019]

3. Payment of Claims

a. In liquidation cases

(1) Distribution to secured creditors. Trustee satisfies secured claims through proceeds from sale of property [§ 363], or abandonment [§ 554] or other disposition [§ 725] of collateral. Also, secured claims may be satisfied through foreclosure or exercise of setoff after obtaining relief from the automatic stay under § 362.

(2) Distribution to unsecured creditors. Dividends [see Rule 3009] paid according to § 726(a) ranking:

(a) First, priority claims [§ 507]

(b) Second, general unsecured claims

(c) Third, tardily filed claims

(d) Fourth, fines, penalties or forfeitures, or multiple, exemplary or punitive damages not compensating for actual, pecuniary loss

(e) Fifth, interest

b. Under chapter 11, 12, or 13 plans

(1) As provided for by the plan

(2) Protections afforded secured claims under the Code. §§ 1111(b), 1129(a)(7), 1129(b)(2)(A), 1225(a)(5), 1325(a)(5).

(3) As to unsecured claims, § 726 order of distribution does not apply [see § 103(b)], but, absent consent, priority claims must be paid [see §§ 1129(a)(9), 1222(a)(2), 1322(a)(2)], and other unsecured claims must receive at least as much as they would have received if § 726 applied [§§ 1129(a)(7), 1225(a)(4), 1325(a)(4)]

(4) Plan payments [Rule 3021]

c. Sale or transfer of claims [Rule 1003]

d. Reaffirmation agreements [§ 524(c)(d)]

e. Other sources of payment -- insurance, guarantees, co-debtors

[updated June 1998]

[63. Creditor's Claims In Bankruptcy Proceedings](#)

[up](#)

[65. Setoff and Recoupment in Bankruptcy -- Setoffs
\(cont'd\), Recoupment](#)



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Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc., and its parent company, Mallinckrodt plc, have agreed to pay \$100 million to settle Federal Trade Commission charges that they violated the antitrust laws when Questcor acquired the rights to a drug that threatened its monopoly in the U.S. market for adrenocorticotrophic hormone (ACTH) drugs. Acthar is a specialty drug used as a treatment for infantile spasms, a rare seizure disorder afflicting infants, as well a drug of last resort used to treat other serious medical conditions.

The FTC's complaint alleges that, while benefitting from an existing monopoly over the only U.S. ACTH drug, Acthar, Questcor illegally acquired the U.S. rights to develop a competing drug, Synacthen Depot. The acquisition stifled competition by preventing any other company from using the Synacthen assets to develop a synthetic ACTH drug, preserving Questcor's monopoly and allowing it to maintain extremely high prices for Acthar.

"Questcor took advantage of its monopoly to repeatedly raise the price of Acthar, from \$40 per vial in 2001 to more than \$34,000 per vial today – an 85,000 percent increase," said FTC Chairwoman Edith Ramirez. "We charge that, to maintain its monopoly pricing, it acquired the rights to its greatest competitive threat, a synthetic version of Acthar, to forestall future competition. This is precisely the kind of conduct the antitrust laws prohibit."

Acthar is a specialty drug used as a treatment for infantile spasms, a rare seizure disorder afflicting infants, and a drug of last resort to treat several other serious medical conditions – including nephrotic syndrome, flare-ups of multiple sclerosis, and rheumatoid disorders. According to the complaint, Acthar treatment for an infant with infantile spasms can cost more than \$100,000.

In Europe, Canada, and other parts of the world, the complaint notes that doctors treat patients suffering from these conditions with Synacthen Depot, which is available at a fraction of Acthar's price in the United States. The complaint alleges that Questcor has consistently viewed Synacthen Depot as a significant competitive threat to its Acthar monopoly in the United States.

The FTC alleges that in June 2013, Questcor acquired the U.S. rights to Synacthen from Novartis AG, outbidding several other companies that were seeking to acquire the rights to Synacthen. Those alternative bidders were interested in developing the drug and had plans to sell it at a significant discount to Acthar's price, capturing a substantial amount of Questcor's business. The FTC charges that Questcor's acquisition of Synacthen stifled competition and eliminated the possibility that an alternative bidder would make the drug available in the U.S. market and compete with Acthar.

In addition to the \$100 million monetary payment, the proposed stipulated court order requires that Questcor grant a license to develop Synacthen Depot to treat infantile spasms and nephrotic syndrome to a licensee approved by the Commission.

A monitor will ensure that Questcor complies with its obligation to grant the license within 120 days of the entry of the order; after that time, a trustee will be appointed to effectuate the license. The order also requires Questcor to provide periodic reports on its efforts, and provide the Commission with advance notice of any future acquisitions of U.S. rights to ACTH drugs.

The states of Alaska, Maryland, New York, Texas and Washington joined in the FTC's complaint. Under the settlement, the states will receive \$10 million from the \$100 million judgment and an additional \$2 million as payment for attorney's fees and costs.

The Commission vote authorizing staff to file the complaint and the proposed stipulated order in federal court was 3-0. Commissioner Maureen K. Ohlhausen issued a concurring statement. FTC staff filed the complaint and proposed order in the U.S. District Court for the District of Columbia.

NOTE: The Commission files a complaint when it has "reason to believe" that the law has been or is being violated and it appears to the Commission that a proceeding is in the public interest. Stipulated orders have the force of law when approved and signed by the District Court judge.

The Federal Trade Commission works to promote competition, and protect and educate consumers. You can learn more about how competition benefits consumers or file an antitrust complaint. Like the FTC on Facebook, follow us on Twitter, read our blogs and subscribe to press releases for the latest FTC news and resources.

PRESS RELEASE REFERENCE:

FTC Approves Sublicense for Synacthen Depot Submitted by Mallinckrodt ARD Inc.

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8/7/2021


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Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, September 4, 2019

Drug Maker Mallinckrodt Agrees to Pay Over \$15 Million to Resolve Alleged False Claims Act Liability for "Wining and Dining" Doctors

Pharmaceutical company Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD Inc. and previously Questcor Pharmaceuticals Inc. "Questcor"), has agreed to pay \$15.4 million to resolve claims that Questcor paid illegal kickbacks to doctors, in the form of lavish dinners and entertainment, to induce prescriptions of the company's drug, H.P. Acthar Gel (Acthar) from 2009 through 2013.

The Federal Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration — which includes money or any other thing of value — with the intent to induce a health care provider to prescribe a drug reimbursed by a federal health care program, including Medicare. This prohibition extends to such practices as "wining and dining" doctors to induce them to write Medicare prescriptions of a company's products.

The government alleged that, from 2009 to 2013, twelve Questcor sales representatives marketing Acthar provided illegal remuneration to health care providers in the form of lavish meals and entertainment expenses. The company paid this remuneration, the government alleges, with the intent to induce Acthar Medicare referrals from those health care providers, resulting in a violation of the Anti-Kickback Statute and the submission of false claims to Medicare.

"The Department of Justice will hold companies accountable for the payment of illegal kickbacks in any form," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "Improper inducements have no place in our federal healthcare system, which depends on physicians making decisions based on the healthcare needs of their patients and not on or influenced by personal financial considerations."

"When companies buy off doctors, patients suffer. My Office is committed to rooting out this type of behavior and the Anti-Kickback Statute is a critical tool in that fight," said U.S. Attorney McSwain. "We will continue to protect the integrity of our healthcare system by holding drug companies accountable for their conduct."

"Paying kickbacks to win business, as contended in this case, cheats taxpayers and the patients who rely on government health care programs for essential care," said Maureen R. Dixon, Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services. "We will continue working with our law enforcement partners to hold accountable entities paying such kickbacks."

The allegations that are the subject of yesterday's settlement were originally alleged in two cases filed under the whistleblower, or qui tam, provision of the False Claims Act. The act permits private parties to sue for fraud on behalf of the United States and to share in any recovery. The act also permits the government to intervene in such actions, as the government previously did in the two whistleblower cases. The whistleblowers will receive approximately \$2.926 million of the settlement. The government is continuing to pursue claims in these two matters alleging that Mallinckrodt violated the False Claims Act by using a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for Acthar. These claims are not being resolved by the settlement.

The government's pursuit of these matters illustrates the government's emphasis on combating healthcare fraud. One of the most powerful tools in this effort is the False Claims Act. Tips and complaints from all sources about potential

8/7/2021 Drug Maker Mallinckrodt Agrees to Pay Over \$15 Million to Resolve Alleged False Claims Act Liability for "Wining and Dining" Doctors | O...

fraud, waste, abuse, and mismanagement can be reported to the Department of Health and Human Services, at 800-HHS-TIPS (800-447-8477).

This matter is being handled by the Civil Division's Commercial Litigation Branch and the U.S. Attorney's Office for the Eastern District of Pennsylvania, with assistance from the U.S. Department of Health and Human Services Office of Inspector General. The two lawsuits are captioned *United States of America ex rel. Strunck et al. v. Mallinckrodt ARD, Inc.*, No. 12-CV-0175 (E.D. Pa.) and *United States of America ex rel. Clark v. Questor Pharmaceuticals, Inc.*, No. 13-CV-1776 (E.D. Pa.).

The claims resolved by this settlement are allegations only and there has been no determination of liability.

Topic(s):

False Claims Act

Component(s):

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13
14 **UNITED STATES DISTRICT COURT**
15 **CENTRAL DISTRICT OF CALIFORNIA**
16 **WESTERN DIVISION**
17

18 HUMANA INC.,
19 Plaintiff,
20 v.
21

22 MALLINCKRODT ARD LLC (f/k/a
23 Mallinckrodt ARD Inc., f/k/a Questcor
24 Pharmaceuticals, Inc.),
25 Defendant.
26

Case No. 2:19-cv-06926-DSF-MRW

DEMAND FOR JURY TRIAL

Honorable Dale S. Fischer
United States District Judge

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SECOND AMENDED COMPLAINT

Plaintiff Humana Inc. (“Plaintiff” or “Humana”), complains against Defendant, Mallinckrodt ARD LLC, formerly known as Questcor Pharmaceuticals, Inc. (“Questcor”)(“Defendant,” “Mallinckrodt,” or the “Company”), as follows:

I. INTRODUCTION

1. This action arises from one of the most outrageous price-gouging schemes in the history of American medicine.

2. H.P. Acthar Gel (“Acthar”) is a drug that has been available since 1952, and for nearly half a century, its price was modest. In 2001, a vial of the drug cost \$40.

3. But by 2018, the same vial cost over \$39,000. This is a 97,500% price increase. It is as if the price of milk increased from \$3 to over \$2,900 per gallon, or a mortgage payment rose from \$2,000 to over \$2 million per month.

4. These eye-popping price increases are not an accident, a market anomaly, or a necessary byproduct of legislation. They are the intended result of purposeful and illegal conduct by Acthar’s producers, Mallinckrodt and its predecessor Questcor. This conduct consists of a complex, multipart scheme involving monopoly, bribery, racketeering, fraud, and other deceptive and unfair practices that have imposed exorbitant and pointless costs on those financially responsible for the costs of the drug, including not just patients but also health and Medicare insurers like Humana, the plaintiff here.

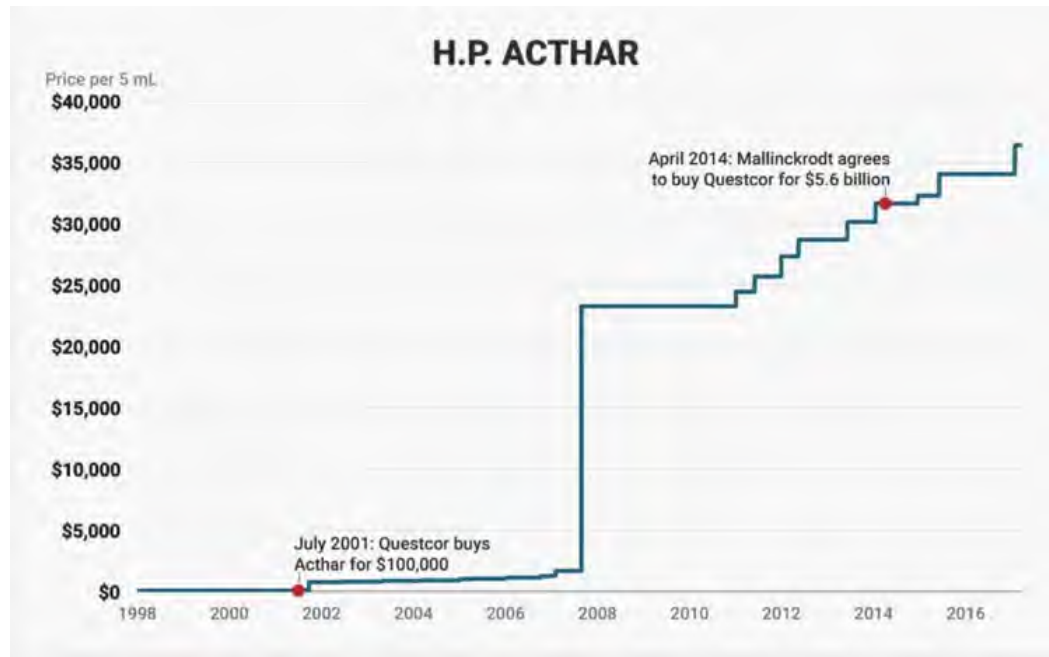
5. Though Acthar may be a billion-dollar golden goose for Mallinckrodt today, its origins were humble. The drug is an adrenocorticotrophic hormone (“ACTH”) analogue produced from the pituitary gland of pigs. It was invented in the late 1940s by the meat company Armour, as a byproduct of pork-processing operations. At the time, Acthar was considered a miracle drug because it stimulated the body’s production of cortisol, provoking a natural anti-inflammatory response that was beneficial for the treatment of various conditions. Acthar was given broad approval by the FDA in 1952

1 to treat a wide range of ailments at a time when such broad approvals were
2 commonplace and did not require support from clinical trials.

3 6. This also occurred before the commercial development of synthetic steroid
4 drugs (corticosteroids) and many popular non-steroidal anti-inflammatory drugs
5 (NSAIDs), such as ibuprofen. The advent of these safe, cheap alternative treatments in
6 pill form reduced the need for an injectable drug derived from the pituitary gland of
7 pigs. These developments completely redefined the economic market for Acthar and
8 rendered it a niche, specialty drug. By the 1990s, Acthar remained medically and
9 economically viable for only a few key uses. For example, Acthar remains the standard
10 of care for infantile spasms, a rare but catastrophic epileptic syndrome affecting babies
11 and toddlers two years old or younger. But other than this and a handful of similarly
12 rare conditions, Acthar is—especially for older patients who are Medicare beneficiaries,
13 such as Humana members—either a drug of last resort or not known to be clinically
14 effective.

15 7. Consequently, the drug became unprofitable for its manufacturer, Aventis
16 Pharmaceuticals, Inc., which had considered stopping production. But the drug was
17 saved in 2001, when Mallinckrodt's predecessor Questcor purchased the right to
18 produce this unprofitable and largely outdated drug for \$100,000 plus modest royalties,
19 seeing it as a potential gold mine for exploitation.

20 8. Thereafter began a run of outrageous price increases. The cost of Acthar
21 ballooned from \$40 in 2001, to \$750 immediately after it was acquired, to \$1,650 by
22 2007. In that year the price was jacked up to \$23,269 per vial. But the increases did not
23 stop or reverse course: instead the price of Acthar was increased eight more times so
24 that by 2018, the drug cost \$38,892 per vial. And since treatment with Acthar usually
25 requires at least three vials, a single course of treatment can cost nearly \$120,000. The
26 following charts the course of Acthar pricing:
27
28



9. In just over a decade, Acthar went from a nearly extinct, financial sinkhole to a billion-dollar cash machine. In August 2014—in the midst of this meteoric price rise—Questcor merged into Mallinckrodt in a deal worth approximately \$5.6 billion. At the time, Acthar was the only drug product sold by Questcor.

10. Mallinckrodt has been able to inflate and maintain the shocking price increases of Acthar mainly through three types of improper conduct.

11. *First*, Mallinckrodt eliminated the competition. It did so by acquiring and then shelving the rights to Acthar’s much cheaper synthetic equivalent ACTH, a drug called Synacthen Depot (“Synacthen”). Drug giant Novartis AG (“Novartis”) was already selling Synacthen in Europe, Asia, and Latin America, but the drug was not approved for use in the United States. After Novartis launched an auction for Synacthen, Mallinckrodt substantially outbid the competition for the rights to Synacthen in the U.S. But rather than undertake the process of obtaining FDA approval for the only drug that was a direct competitor of its best-selling product, Mallinckrodt never seriously attempted to bring Synacthen to market for any clinical use for which Acthar was approved. This kept the price of Acthar artificially high. In addition, Mallinckrodt vertically integrated its sales by distributing Acthar exclusively through

1 the specialty pharmacy CuraScript. CuraScript had no role in decisions on Acthar's
2 pricing. Because of Mallinckrodt's anticompetitive behavior, the FTC and several states
3 sued it for antitrust violations and later reached a \$100 million settlement, as well as an
4 agreement that Mallinckrodt would sublicense its Synacthen rights to a third party.

5 12. *Second*, Mallinckrodt increased and then maintained artificially high
6 demand for Acthar by using a charitable foundation for the illegal purpose of paying
7 patient co-pays. This fund—initially called the Chronic Disease Fund, now doing
8 business as Good Days—provided “patient assistance” funds for Acthar only, and not
9 for other drugs. Mallinckrodt financed the foundation, directed patients to the fund, paid
10 their co-pays as “donations,” and then marketed the drug as “free.” In other words, it
11 was a bribe to patients and a vehicle through which Mallinckrodt could persuade
12 physicians that the astronomical price of the drug should not be a barrier to prescribing
13 it. It also constituted a fraud on Medicare, which is why the Department of Justice
14 recently brought claims against Mallinckrodt under two federal statutes, the False
15 Claims Act, 31 U.S.C. §§ 3729-3733, and the Anti-Kickback Statute, 42 U.S.C. §
16 1320a-7b(b). In addition, this conduct constituted a fraud on Humana (one of the
17 nation's largest sponsors of Medicare Advantage plans) and an intentional interference
18 in Humana's relationship with its insureds, because it removed the incentive for patients
19 to exercise the responsibility ordinarily imposed by co-pays, deductible limits, and
20 other out-of-pocket costs set forth in Humana's agreements with its insureds.

21 13. *Third*, Defendant simultaneously maintained this artificially high demand
22 through a pervasive bribery scheme to doctors. It should go without saying that doctors
23 would not otherwise be inclined to prescribe, what for most purposes is an antiquated
24 and expensive drug that requires refrigeration and injection, when cheaper, more
25 effective pills and remedies were available. Furthermore, though Acthar is a first-line
26 treatment for infantile spasms, that market is small and Mallinckrodt sought to redirect
27 its marketing efforts away from the poor public-relations consequences of earning
28 billions of dollars off the backs of sick children. Consequently, Mallinckrodt

1 aggressively marketed the drug for the treatment of conditions more common among
2 adult patients, including those eligible for Medicare. So under the guise of “education”
3 and “marketing,” Mallinckrodt paid millions of dollars to thousands of doctors to
4 encourage the use of Acthar even for conditions where it is not the first-line treatment.
5 Though payment of modest expenses to doctors by pharmaceutical companies may
6 frequently be lawful and harmless, here Mallinckrodt crossed well over the line by
7 paying thinly disguised bribes to at least 20 doctors—mainly rheumatologists,
8 neurologists, and nephrologists—responsible for a significant number of prescriptions.
9 Mallinckrodt paid this group of physicians at least \$250,000 each over a three-year
10 period. Not surprisingly, physicians who received more than \$10,000 from
11 Mallinckrodt prescribed more than double the amount of Acthar as those who received
12 \$25 or less. Also not surprising: fewer than 10% of Acthar prescriptions are now for
13 treatment of infantile spasms.

14 14. Humana, a Medicare Part D provider, has paid more than \$700 million
15 over more than eight years for Acthar. It paid an inflated price due to Mallinckrodt’s
16 monopolization and racketeering, and reimbursed unnecessary Acthar treatments due to
17 the prescribing doctors’ misrepresentations that they had not received any illegal
18 kickbacks. By this action, Humana seeks to recoup from Mallinckrodt its ill-gotten
19 gains.

20 II. PARTIES

21 15. **Humana.** Plaintiff Humana Inc. (“Humana”) is a Delaware corporation
22 with its principal place of business at 500 West Main Street, Louisville, Kentucky.
23 Humana and its subsidiaries are providers of healthcare related services, including
24 insuring risk for prescription drug costs for more than eight million members in all 50
25 states, the District of Columbia, and Puerto Rico. More than 75% of Humana’s total
26 premium revenues in the year 2012 were derived from contracts with the federal
27 government, including Medicare Part D prescription drug coverage and Medicare
28 Advantage plans. Humana operates its insurance businesses through a variety of wholly

1 owned subsidiaries, all of which have assigned their relevant claims in this action to
2 Humana.¹

3 16. **Mallinckrodt.** Defendant Mallinckrodt ARD LLC has its principal place
4 of business at 1425 Route 206, Bedminster, NJ, 07921. Mallinckrodt ARD LLC was
5 previously named Mallinckrodt ARD, Inc., and before that was named Questcor
6 Pharmaceuticals, Inc.

7 17. Mallinckrodt ARD LLC is a subsidiary of Mallinckrodt plc, an Irish public
8 limited company. On April 4, 2014, Mallinckrodt plc entered into an Agreement and
9 Plan of Merger with Questcor and absorbed Questcor as a wholly owned subsidiary on
10 August 14, 2014 for approximately \$5.6 billion.

11 18. Questcor survived the merger as a wholly owned indirect subsidiary of
12 Mallinckrodt plc and continued to market Acthar thereafter, until changing its name to
13 Mallinckrodt ARD, Inc. on July 27, 2015.

14 19. On January 26, 2019, Mallinckrodt ARD, Inc. converted to Mallinckrodt
15 ARD LLC and it continues to market Acthar to this day.

16 20. **Mallinckrodt's Unnamed Agents and Co-Conspirators.** Mallinckrodt
17 was joined in its scheme by several persons or groups of persons who served as agents,

18 ¹ Some of the subsidiaries through which Humana conducts insurance business
19 include: Arcadian Health Plan, Inc., CarePlus Health Plans, Inc., Cariten Health Plan,
20 Inc., Cariten Insurance Company, CHA HMO, Inc., CompBenefits Insurance Company,
21 Emphesys Insurance Company, Health Value Management, Inc. d/b/a ChoiceCare
22 Network, Humana Behavioral Health, Inc., HumanaDental, Inc., Humana Benefit Plan
23 of Illinois, Inc., Humana Employers Health Plan of Georgia, Inc., Humana Health
24 Benefit Plan of Louisiana, Inc., Humana Health Company of New York, Inc., Humana
25 Health Insurance Company of Florida, Inc., Humana Health Plan of California, Inc.,
26 Humana Health Plan of Ohio, Inc., Humana Health Plan of Texas, Inc., Humana Health
27 Plan, Inc., Humana Health Plans of Puerto Rico, Inc., Humana Insurance Company,
28 Humana Insurance Company of Kentucky, Humana Insurance Company of New York,
Humana Medical Plan of Michigan, Inc., Humana Insurance of Puerto Rico, Inc.,
Humana Medical Plan of Pennsylvania, Inc., Humana Medical Plan of Utah, Inc.,
Humana Medical Plan, Inc., Humana Pharmacy Solutions, Inc., Humana Regional
Health Plan, Inc., and Humana Wisconsin Health Organization Insurance Corporation.

1 co-conspirators, aiders and abettors, or otherwise acted in concert in connection with
2 Mallinckrodt's Acthar price schemes that have not been named as defendants in this
3 matter but are nonetheless important to the claims herein.

4 21. The Competitor. Novartis marketed and sold Synacthen outside of the
5 United States, and owned exclusive rights to sell Synacthen in the U.S. On information
6 and belief, Novartis agreed to sell the Synacthen U.S. rights to Questcor with
7 knowledge that Questcor did not intend to bring Synacthen to market to compete with
8 Acthar.

9 22. The Consultant. BioSolutia Inc., now known as CareMetx, LLC
10 ("BioSolutia") is a Maryland-based firm that provided health-care consulting services to
11 Mallinckrodt, including through an individual consultant (the "BioSolutia Consultant")
12 who was retained full time to work on Acthar, and who helped design and implement
13 Mallinckrodt's schemes.

14 23. The Agents. Acthar is a "specialty pharmaceutical" and generally
15 unavailable at most retail pharmacies. It is instead available primarily through specialty
16 pharmacies, which focus on high-cost, high-complexity, and/or high-touch medication
17 therapy for patients with complex disease states.

18 24. Because of this, in June 2007, Mallinckrodt agreed with Express Scripts
19 Holding Company ("Express Scripts"), a Missouri-based pharmacy benefit
20 management company, to provide integrated services critical to the scheme and to do so
21 through certain of Express Scripts' subsidiaries. Each of these subsidiaries had separate
22 functions, but their coordinated purpose was to support and maintain Mallinckrodt's
23 inflated Acthar prices, including by acting as Mallinckrodt's agent for purposes of
24 pricing.

25 25. Priority Healthcare Distribution Inc., doing business as CuraScript SD
26 ("CuraScript"), a Florida-based specialty pharmacy distributor, served as
27 Mallinckrodt's exclusive distributor for Acthar. CuraScript was engaged by
28 Mallinckrodt to deliver Acthar to the network of specialty pharmacies (including

1 Humana Pharmacy), who then deliver the medicine to patients' homes. CuraScript may
2 have been aided in this function by CuraScript, Inc., doing business as CuraScript SP
3 Specialty Pharmacy, which itself operates specialty pharmacies in the United States.
4 Both CuraScript and CuraScript SP Specialty Pharmacy were subsidiaries of Express
5 Scripts.

6 26. United BioSource Corporation, formerly known as HealthBridge and now
7 known as United BioSource LLC ("UBC"), a Pennsylvania-based company, provided
8 pharmaceutical support services. During most of the relevant time period, UBC was
9 also an Express Scripts subsidiary, though Express Scripts completed its sale of UBC to
10 a private equity firm in 2018. UBC designed and operationalized patient access centers
11 that assist patients and prescribers with navigating prescription drug coverage and
12 pharmacy options through patient access programs, including patient assistance
13 programs, reimbursement, alternate funding, and compliance services. UBC was
14 engaged by Mallinckrodt to act as the administrator for the reimbursement of Acthar,
15 interacting directly with patients and third-party payors by coordinating various patient-
16 assistance programs, including the ASAP and PAP programs described further below.

17 27. Accredo Health Group, Inc., doing business as Liberty Pennsylvania,
18 Medco Health Solutions, Liberty Texas, Gentiva, or Gentiva Health Services
19 ("Accredo"), is also an Express Scripts subsidiary. Accredo is a specialty pharmacy
20 services company that assists patients in obtaining medications, including by
21 advocating for insurance coverage of the drug.

22 28. As applied to Acthar, UBC acted as the hub between these entities,
23 designing and coordinating Acthar's sale, distribution, and reimbursement through its
24 patient access programs. So, for example, when a doctor prescribes an initial or renewal
25 course of Acthar to a patient, the prescription is sent to the "Acthar Hub" and a case
26 manager is assigned to the patient through UBC or Accredo, which performs
27 administrative services associated with obtaining insurance coverage of the drug from
28 insurers such as Humana. Payment by the insurer or other payor is then made to

1 CuraScript, which ships the medication to specialty pharmacies or directly to the
2 patient. As set forth further below, CuraScript has no role in setting the price, which is
3 functionally set by Mallinckrodt alone. CuraScript merely acts as Mallinckrodt's agent,
4 collecting payment and shipping the medication.

5 29. The Charity. Chronic Disease Fund, Inc. ("CDF") is a Texas-based
6 501(c)(3) organization that now goes by the name Good Days From CDF or simply
7 Good Days. Its putative mission is to provide co-pay assistance and other financial
8 support to patients who meet the charity's application criteria.

9 30. The Prescribing Doctors. Mallinckrodt paid certain physicians (the
10 "Prescribing Doctors") substantial sums to promote Acthar over other treatments. The
11 Prescribing Doctors agreed with Mallinckrodt to promote and prescribe Acthar without
12 disclosing to Humana or other payors their remuneration from Mallinckrodt. Not all of
13 the Prescribing Doctors are known to Humana, and discovery is needed to identify them
14 fully.

15 **III. JURISDICTION AND VENUE**

16 31. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331,
17 because this action arises under the laws of the United States, including the Sherman
18 Act, 15 U.S.C. § 1, *et seq.*, and 28 U.S.C. § 1964(c), because this action alleges
19 violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18
20 U.S.C. § 1962.

21 32. This Court has personal jurisdiction over the Defendant pursuant to 15
22 U.S.C. § 22 because it transacts business in this district and may be found here.

23 33. This court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367 over
24 violations of state law, including state common law claims.

25 34. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and
26 (c), and 18 U.S.C. § 1965.

27 35. A substantial part of the events giving rise to this action occurred in this
28 judicial district. Questcor Pharmaceuticals Inc.—later renamed Mallinckrodt ARD

1 Inc.—was until January 26, 2019 a California corporation. The successor to
2 Mallinckrodt ARD Inc., Mallinckrodt ARD LLC is a limited liability corporation
3 organized under the laws of California. Prior to its 2014 acquisition by Mallinckrodt,
4 Questcor was headquartered in Anaheim, California, in this judicial district. Several of
5 the co-conspirator Prescribing Doctors are also located in the state of California,
6 including one Prescribing Doctor whose offices are located in Los Angeles, California
7 in this judicial district. Furthermore, Humana has more than 575,000 insureds in the
8 state of California. Humana’s operating subsidiary in California, Humana Health Plan
9 of California, is located in Irvine, California in this judicial district.

10 **IV. FACTUAL ALLEGATIONS**

11 **A. Humana**

12 36. Congress established Medicare in 1965 to provide health insurance
13 coverage for people aged sixty-five or older and for people with certain disabilities or
14 afflictions. In 2003, Congress established a voluntary prescription drug benefit program
15 for Medicare enrollees known as Medicare Part D. Under Medicare Part D, Medicare
16 contracts with private entities, known as Part D Plan Sponsors, to administer
17 prescription drug plans.

18 37. Under the Medicare statute, a Part D beneficiary may be required to make
19 a partial payment for the cost of prescription drugs in the form of a co-payment,
20 coinsurance, or deductible (collectively “co-pays”). The co-pays can be substantial for
21 expensive medications and vary throughout the year, depending on a beneficiary’s total
22 Part D covered expenses incurred that year up to that point.

23 38. Medicare co-pays exist to encourage physicians and beneficiaries to be
24 efficient consumers of federally reimbursed health care products, while also
25 encouraging those manufacturing such products to price them based on market forces
26 such as consumer sensitivity and competition. Manufacturers paying the Medicare co-
27 pays of those seeking to buy their drug circumvent this congressionally designed check
28 on health care costs. As the United States Department of Health and Human Services,

1 Office of the Inspector General has observed, drug manufacturers paying the Medicare
2 Part D co-pays of patients taking their products “eliminat[e] a market safeguard against
3 inflated prices.” HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs
4 for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625 (Nov. 22, 2005).

5 39. Humana operates or administers Medicare Part D plans on behalf of the
6 federal and state governments for millions of members. Humana also provides coverage
7 for pharmaceuticals, including Acthar, through other plans, including medical insurance
8 (Medicare Part B), Medicare Advantage (Medicare Part C), Medicaid, and commercial
9 healthcare plans. Through its administration of these plans, Humana bears significant
10 risk that the costs and utilization of healthcare services will rise. When Humana
11 assumes these risks it relies in large part on the protections afforded by law against
12 submissions of false or fraudulent claims to government healthcare providers.

13 40. Humana’s agreements with its providers include a provision that requires
14 the provider to certify its compliance with state and federal law, as well as rules
15 promulgated by government entities such as the Centers for Medicare & Medicaid
16 Services (“CMS”), a division of the Department of Health and Human Services that
17 administers Medicare and Medicaid. These contractual provisions are essential for
18 Humana to ensure that it receives prompt payments and reimbursements from CMS for
19 valid claims, and to ensure that it does not pay invalid claims that might increase costs
20 to both itself and Medicare.

21 **B. Acthar**

22 41. Acthar is an ACTH analogue used as an anti-inflammatory. Though its
23 exact mechanism of operation is unclear, it is believed to stimulate the body’s own
24 steroidal hormones (such as cortisol and corticosterone), as well as to affect the body’s
25 steroid-independent immunomodulatory and anti-inflammatory pathways.

26 42. Acthar’s active ingredient is extracted from pig pituitary glands. It was
27 invented in 1948 by the pharmaceutical division of the Armour meatpacking and
28 processing company. The original form of ACTH has a half-life of only 10 minutes, so

1 Acthar was developed for clinical use by creating a repository gel tailored to a patient's
2 individual needs. The gel must be refrigerated and is applied through either an
3 intramuscular or a subcutaneous depot injection (i.e., an injection that deposits the drug
4 in a localized mass, which is gradually absorbed by the body over an extended period).

5 43. Acthar's invention either was roughly contemporaneous with, or preceded,
6 the development of certain corticosteroids, a class of steroids that can also be used to
7 fight inflammation. Well-known examples of corticosteroids include hydrocortisone
8 and prednisone. Acthar's invention also predated the discovery of ibuprofen and certain
9 over-the-counter NSAIDs in pill form that are also used to combat inflammation.

10 44. The U.S. Food and Drug Administration ("FDA") first approved Acthar
11 for marketing in the United States in 1952. This was before drugs were required to
12 demonstrate "substantial evidence" of the efficacy for a marketed indication. Its original
13 label lacked evidence from controlled clinical trials.

14 45. Acthar was approved to treat multiple sclerosis ("MS") in 1979. Today, it
15 is approved for treatment of exacerbations of MS and also for indications of diseases
16 and disorders that include rheumatic, collagen, dermatologic, and allergic states, as well
17 as ophthalmic, respiratory, and edematous states. Specifically, these include idiopathic
18 membranous nephropathy, the largest single cause of nephrotic syndrome, a kidney
19 disorder; rheumatoid arthritis; dermatomyositis and polymyositis (inflammatory
20 diseases of the skin and muscles); symptoms of sarcoidosis (a disease that mainly
21 affects the lungs and lymph glands); and inflammatory conditions of the eye.

22 46. However, there remains a lack of evidence to support the use of Acthar for
23 most indications. The clinical evidence supporting the effectiveness of Acthar in
24 treating some of these conditions consists of small (fewer than 25 participants)
25 uncontrolled trials and case reports. For many of these conditions, Acthar is not
26 considered the first-line treatment.

27 47. Acthar was owned first by Armour Pharmaceutical Company, then by
28 Rhone-Poulenc Rorer, and until 2001 by Aventis (now Sanofi). To that point, the drug

1 was priced relatively more competitively with other anti-inflammatories.² But since it
2 was expensive to produce, difficult to apply, and (except for certain indications such as
3 infantile spasms) not known to be more effective than simpler, cheaper, and more
4 widely available drugs, Aventis considered discontinuing production. Questcor acquired
5 worldwide rights to sell and manufacture Acthar from Aventis in July 2001. In view of
6 what would come, the price was a pittance: \$100,000, plus modest royalties.

7 **C. Medical Use of Acthar and Other Adrenal Hormone Drugs**

8 48. Corticotropin, the active ingredient in Acthar, is classified by United States
9 Pharmacopeia (USP) in its Drug Classification system under “Hormonal Agents,
10 Stimulant/ Replacement/ Modifying (Adrenal).” Among the other drugs in this
11 category are prednisone, hydrocortisone, dexamethasone, and other corticosteroids.
12 Each of these drugs affects the levels of the hormone cortisol in the body. This broad
13 class of drugs is the one from which medical providers may choose a drug with the
14 same basic biological mechanism of action.

15 49. For example, with the sole exception of infantile spasms,³ prednisone is
16 approved by the FDA to treat all of the same diseases and disorders as Acthar.
17 Therefore it is not surprising that when Acthar is compared with other drugs by the
18 medical research community, those comparisons are almost universally made to

19 _____
20 ² Even then, Acthar was still more than quadruple the cost of corticosteroids, making it
21 far less than a perfect economic substitute. When purchased from Aventis, a two-to-
22 three vial course of Acthar treatment cost approximately \$80 to \$120, whereas a course
of treatment with corticosteroids typically costs \$20 or less.

23 ³ Only one other drug, Sabril (vigabatrin), has FDA approval for treatment of infantile
24 spasms. Sabril is not a steroid, but is instead in a class of anticonvulsant drugs that are
25 used to treat epilepsy. Sabril works by inhibiting the breakdown of a particular neural
26 transmitter. Sabril may be used in combination with long-acting ACTH drugs, or it may
27 be suitable where long-acting ACTH drugs have been ineffective at controlling infantile
28 spasms or were not well tolerated by the patient. Although long-acting ACTH drugs and
Sabril may both be used to treat infantile spasms, they are not medical substitutes for
one another because of their different biological mechanisms of action.

1 corticosteroids. Indeed, Mallinckrodt itself prominently references a comparative study
2 between Acthar and prednisone for the treatment of infantile spasms on its website.
3 Additionally, Acthar has been compared to intravenous methylprednisolone for
4 treatment of MS relapses and to prednisone for treatment of sarcoidosis.

5 50. For most of Acthar's indications, there is a lack of medical evidence to
6 support its use over prednisone or any other corticosteroid medication. Acthar has
7 similar pharmacodynamic effects as corticosteroids, but it must be administered through
8 an injection, as opposed to a pill, and it must be refrigerated. Although this difference
9 alone would be enough to make Acthar an undesirable substitute for corticosteroids, its
10 astronomical cost is also a major factor in the medical community's preference for
11 corticosteroids over Acthar. Prednisone, which is available as a generic medication
12 made by many manufacturers, can cost as little as \$0.20 per pill (less than \$20 for a
13 typical course of treatment) as compared to the \$39,000 per-vial cost of Acthar (or
14 \$117,000 for a three-vial treatment). Due to the lack of medical data supporting the use
15 of Acthar over more convenient and cheaper corticosteroids, a question remains why
16 Acthar or other long-acting ACTH drugs are prescribed at all. Part of the answer to that
17 question is certainly the illegal co-payment and bribery schemes described below, but
18 that does not appear to be the full story. Acthar also appears to be viewed by certain
19 providers or patients as distinct from corticosteroids.

20 51. Despite its classification within a broad group of "Hormonal Agents"
21 acting on the adrenal system by USP, Acthar is considered to be distinct from the
22 corticosteroid drugs within the classification for several reasons. First, Acthar's
23 mechanism of action is slightly different from that of corticosteroids. As Mallinckrodt
24 describes in its marketing literature for Acthar: "Acthar is not a steroid. But one of the
25 ways it is thought to work is by helping your body produce its own natural steroid
26 hormones." Second, studies funded by Mallinckrodt have been published that claim to
27 show clinical evidence supporting the superiority of Acthar compared with
28 corticosteroid drugs. Mallinckrodt has aggressively marketed these studies and their

1 conclusions to physicians. Third, Acthar is supposed to be a last-line treatment
2 alternative that may be tried after corticosteroids have failed in the hope that Acthar,
3 through its slightly different mechanism of action, may be effective where similar drugs
4 have not been. In language on Acthar's label required by the FDA, it was noted that
5 "corticosteroid therapy is considered to be the treatment of choice" relative to Acthar,
6 unless the condition is unresponsive to corticosteroid therapy. Mallinckrodt further
7 explains to its investors that Acthar "may not be prescribed unless a clear benefit in
8 efficacy or safety is demonstrated or until alternatives have failed to provide positive
9 patient outcomes or are not well tolerated by the patient."⁴ Humana, similar to many
10 other insurers, likewise limits approved use of Acthar (other than for infantile spasms)
11 under its policies to patients who have "contraindications or intolerance to
12 corticosteroids that are not expected to also occur with" Acthar.

13 52. These distinctions are further evidenced by Acthar's assignment to a
14 different Standard Therapeutic Class than corticosteroids in the widely-used First Data
15 Bank (FDB) drug database.⁵ Corticosteroids like prednisone are in FDB's
16 "Glucocorticoids" Standard Therapeutic Class. In contrast, FDB classifies Acthar in
17 the "Adrenocorticotrophic Hormones" Standard Therapeutic Class. The only other
18 drugs in the "Adrenocorticotrophic Hormones" Standard Therapeutic Class are
19 Synacthen and several short-acting (non-depot) formulations of natural and synthetic
20 ACTH which are approved by the FDA only for use in the testing of adrenal function.⁶

21 ⁴ The only exception is that Acthar may be considered the most effective, "first-line"
22 treatment for infantile spasms.

23 ⁵ Humana utilizes information from both FDB and USP to classify drugs according to
24 their therapeutic class in the normal course of its business.

25 ⁶ These short-acting ACTH drugs (Acthrel and Cortrosyn) are not appropriate medical
26 substitutes for Acthar because there is no overlap in the medical conditions that the
27 drugs are approved to treat or diagnose. Acthar is not indicated to diagnose adrenal
28 insufficiency and the short-acting ACTH drugs are indicated only for use in that
diagnosis. Moreover, the short-acting nature of these drugs makes them impractical for

D. Mallinckrodt's Monopoly Power with Acthar

1. Direct Evidence of Monopoly Power

53. Mallinckrodt has exercised monopoly power in the United States with Acthar. Ever since its acquisition of marketing rights in 2001, Mallinckrodt has charged supracompetitive prices for the drug.

54. Immediately after acquiring the rights to sell Acthar, Mallinckrodt's predecessor company Questcor increased the price from approximately \$40 per vial to nearly \$750 per vial.

55. By the end of 2006, Acthar accounted for 94 percent of Questcor's net sales. On August 27, 2007, Questcor increased the price of Acthar by more than 1,300% overnight, from \$1,650 to \$23,269 per vial. The decision to charge tens of thousands for a vial of Acthar was spearheaded by Questcor's chief executive, Don Bailey, who spent most of his career as an executive with a defense contractor, not in the pharmaceutical industry.

56. Questor has since raised the price of Acthar on multiple occasions since 2011 to \$38,892 in 2018.

57. Acthar net sales increased from \$218 million in 2011 to more than \$1 billion in 2015.

58. Medicare spending on Acthar increased geometrically from 2011 to 2015, with total spending of nearly \$2 billion and more than \$600 million in 2016 alone. The following chart reveals how the number of Medicare Part D claims for Acthar has grown by more than 700% from 2011 to 2016:

treatment of the chronic or persistent conditions that long-acting ACTH drugs are designed to treat. Short-acting ACTH drugs would need to be given intravenously or at frequent intervals in order to have the same effect. Therefore only long-acting ACTH drug formulations can be considered medically appropriate substitutes for Acthar.

Year	Claim Count	Total Spending
2011	1,471	\$49,456,911
2012	3,387	\$141,451,608
2013	6,752	\$262,581,602
2014	9,611	\$391,189,653
2015	11,209	\$503,999,371
2016	12,867	\$636,174,840
Total:	45,297	\$1,984,853,985

2. Further Evidence of Monopoly Power

59. Several factors constitute further evidence of Mallinckrodt's monopoly power.

60. Lack of Competition. Mallinckrodt does not set the price of Acthar by reference to other adrenal hormone drugs prescribed to treat the same indications that Acthar treats. Acthar is priced substantially higher than corticosteroid drugs used to treat the same indications. This suggests that there is no competitive constraint on Mallinckrodt's ability to set prices. Indeed, Acthar represents 100% of the sub-market for long-acting ACTH drugs available in the United States.

61. Although Acthar may face limited competition at the margin from other drugs in the broader adrenal hormone class, in practice it competes almost entirely in a separate market (or submarket) for long-acting ACTH drugs. In the United States, Acthar is the only long-acting ACTH drug approved by the FDA. Mallinckrodt acknowledges this in its own financial filings, stating that "Acthar Gel has limited direct competition due to the unique nature of the product." Acthar may have some medical similarity to other drugs in the adrenal hormone class, but economically it is in a distinct market.

62. This lack of competition is further evidenced by Acthar's low rates of substitution for other adrenal hormone drugs. Humana's data on prescriptions of Acthar show that from 2011 to 2019, the price of Acthar increased 59% while the price of Glucocorticoid drugs *decreased* by 5%. During the same period, the quantity of

1 Acthar reimbursed by Humana increased 273%, while the quantity of Glucocorticoid
2 drugs reimbursed *decreased* by 22%. This shows that while Glucocorticoid drugs got
3 cheaper relative to Acthar, the amount of Acthar prescribed increased. If Acthar were
4 viewed as an economic substitute for Glucocorticoid drugs, users of Acthar would have
5 switched as Glucocorticoids became relatively cheaper. In practice, it appears that there
6 was little or no substitution from Acthar to Glucocorticoid drugs as a result of Acthar's
7 rising prices. Glucocorticoid drugs are Acthar's closest medical substitute but Acthar's
8 use grew completely independently of their pricing, indicating that Glucocorticoids
9 operate as part of a separate economic market.

10 63. This measure of substitution is expressed in economic terms as the cross-
11 price elasticity of demand. In order for products to be considered close economic
12 substitutes, they should have a cross-price elasticity above the value 2.0 (positive).
13 Values close to zero or negative indicate little or no economic substitution. The cross-
14 price elasticity demand for Acthar versus the Standard Therapeutic Class of
15 Glucocorticoids is *negative* 0.1, showing a very low degree of substitution between
16 Acthar and Glucocorticoid drugs.

17 64. Acthar also has a low cross-price elasticity of demand with the short-acting
18 ACTH diagnostic agents included in its Standard Therapeutic Class. Humana's data
19 show that the cross-price elasticity between Acthar and these drugs is *negative* 1.0.
20 These short-acting drugs are also rarely used. Acthar represented more than 99% of all
21 drugs purchased for Humana members within the Standard Therapeutic Class of
22 Adrenocorticotrophic Hormones from 2011 to 2019.

23 65. One of the main reasons for the absence of competition with Acthar is the
24 unavailability of Synacthen, a close medical and economic substitute. Mallinckrodt's
25 conduct with respect to Synacthen is addressed further below.

26 66. Enhanced Profitability. Acthar's post-2011 price increases were effective,
27 however, at increasing Mallinckrodt's profits because they did not result in much, if
28 any, loss of volume to drugs that are potential medical substitutes such as

1 Glucocorticoids. Mallinckrodt's revenues on Acthar grew from \$218 million in 2011 to
2 \$953 million in 2019. Mallinckrodt's profits on Acthar likewise increased by hundreds
3 of millions of dollars per year during the period from 2011 to 2019. Mallinckrodt
4 therefore exercised its monopoly power by profitably pushing through significant and
5 durable price increases on Acthar after 2011.

6 67. Mallinckrodt restricted output of Acthar in order to achieve this pricing.
7 Had Acthar been offered at a lower price, similar to the price Synacthen is sold at in
8 other countries or similar to the price Acthar used to be sold at by Aventis, demand for
9 the product would increase because more people who want long-acting ACTH drugs
10 would be able (or willing) to afford them. Instead, Mallinckrodt has upped the price of
11 Acthar each year such that its price increased by nearly 60% since 2011, suppressing
12 demand and output of Acthar relative to what it would have been if Synacthen or
13 Acthar were widely available at competitive prices.

14 68. High Barriers to Entry. Despite the lack of patent protection for Acthar, the
15 U.S. ACTH market is still characterized by high barriers to entry. This includes FDA
16 approval, which is required to market drugs to U.S. consumers. Drugs sold outside of
17 the U.S. are therefore not viable substitutes.

18 69. Furthermore, developing a safe, effective, and reliable substitute would
19 require substantial investments of resources and time, with no guarantee of success.
20 One would have to source the active ingredient, develop a sustained-release depot-
21 injection formulation, scale production, and conduct clinical trials, particularly because
22 Acthar is derived from a biological and not a chemical process. Mallinckrodt's CEO has
23 assured investors that Acthar "has significant durability in the marketplace" because "it
24 will be very difficult for this product to be replicated in any way [by] a generic."

25 3. Anticompetitive Conduct in the Acquisition of Synacthen

26 70. Synacthen is a synthetic ACTH drug with similar biological activities and
27 pharmacological effects as Acthar. In Europe, Canada, and other parts of the world,
28 doctors treat patients with Synacthen for the same conditions that are treated with

1 Acthar in the U.S. Acthar is not marketed outside of the United States. On information
2 and belief, the reason Acthar is not marketed internationally is because it is not cost
3 competitive with Synacthen.

4 71. Questcor itself considered the drugs so similar that it submitted Synacthen
5 information to support its application to the FDA to expand the label indications for
6 Acthar. It also cited Synacthen studies in its Acthar marketing materials.

7 72. Before June 2013, Novartis marketed and sold Synacthen abroad. For
8 years, Questcor viewed Synacthen as a significant potential competitive threat to its
9 monopoly. Questcor therefore sought to acquire the rights to Synacthen as a defensive
10 move to prevent competitors from acquiring it and developing it as a competitor to
11 Acthar.

12 73. In late 2011, Novartis decided to divest exclusive rights to seek FDA
13 approval for Synacthen and commercialize it in the United States. Dozens of companies
14 contacted Novartis and expressed interest in acquiring Synacthen. Three firms
15 proceeded through several rounds of negotiations with Novartis, submitted formal
16 offers, and drafted near-final agreements.

17 74. Each of the three firms planned to develop and use Synacthen to compete
18 directly with Acthar, and to price Synacthen well below Acthar. The three firms had the
19 necessary expertise and financing, as well as sufficient business and regulatory plans, to
20 develop Synacthen for the U.S. market. The identity of the firms that were denied the
21 development rights to Synacthen on account of Mallinckrodt's anticompetitive conduct
22 were not publicly disclosed by Novartis.

23 75. The Synacthen asset package sold by Novartis included valuable trade
24 secrets, including technical documentation detailing both the precise formulation for the
25 Synacthen drug product and the manufacturing process. Because Synacthen had a long
26 history of safe and effective use abroad, a buyer would not need to begin the research,
27
28

1 development, testing, or manufacturing process from scratch. The asset package would
2 therefore substantially lower the barriers to entry in the U.S. ACTH market.⁷

3 76. The bidding process occurred in late 2012 and early 2013. Questcor signed
4 a confidentiality agreement with Novartis and submitted an offer for Synacthen.
5 Novartis negotiated with the three alternative bidders in parallel with Questcor, and
6 each company had exchanged deal terms with Novartis and had submitted a formal
7 offer. The offers by the three alternative bidders were comparable to each other in value
8 and structured similarly, and included an upfront payment, milestone payments upon
9 FDA approval, and significant royalties on U.S. Synacthen sales. Unlike the three
10 alternative bidders, however, Questcor had only inchoate plans for Synacthen and
11 conducted limited due diligence when it submitted its initial offer to Novartis. It
12 nevertheless submitted a bid several multiples higher than the other bidders.

13 77. On June 11, 2013, Questcor and Novartis entered into a Licensing
14 Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, “the
15 Agreements”), that gave Questcor exclusive rights to develop, market, and sell
16 Synacthen in the United States. Under the Agreements, Questcor is obligated to pay a
17 minimum of \$135 million to Novartis for Synacthen.

18 78. On information and belief, Novartis knew and understood that Questcor
19 did not intend to develop Synacthen. This may be inferred from the fact that Questcor’s
20 bid for Synacthen was substantially higher than that of its competitors, even though
21 Questcor had done far less, and was in a worse position, to bring Synacthen to market.
22 In addition, Novartis was not naïve, and could be expected to understand that Questcor
23 would have little interest in developing the only synthetic competitor to Acthar, its
24 extraordinarily lucrative non-synthetic product.

25 _____
26 ⁷ It is also important to note that a short-acting version of Synacthen, sold under the
27 brand name Cortrosyn, has been approved by the FDA for sale in the United States
28 since 2009. This fact makes it far more likely that the FDA would approve a long-acting
version of the same drug.

1 79. Questcor claimed that it acquired Synacthen to develop it for new, non-
2 Acthar indications, but given the drugs' similarities, any therapeutic indication that
3 Questcor might have pursued with Synacthen could have been pursued with Acthar.

4 80. Fourteen months after acquiring Synacthen, Mallinckrodt acquired
5 Questcor for \$5.6 billion, an amount almost entirely attributable to the value of Acthar.

6 81. Neither Questcor nor Mallinckrodt made more than superficial efforts to
7 pursue commercialization of Synacthen, however. Instead Mallinckrodt chose to shelve
8 the asset and thereby to protect Acthar monopoly pricing.

9 82. This conduct led the U.S. Federal Trade Commission ("FTC"), joined by
10 the states of Alaska, Maryland, New York, Texas, and Washington, to bring an action
11 against Mallinckrodt under the FTC Act, Section 2 of the Sherman Act, and state
12 antitrust laws. On January 18, 2017, the FTC announced that Mallinckrodt had agreed
13 to pay \$100 million to settle the suit. The parties also filed and the court approved a
14 stipulated court order requiring Questcor to grant a license to develop Synacthen to treat
15 infantile spasms and nephrotic syndrome to a licensee approved by the FTC. On July
16 14, 2017, the FTC announced that it had approved a sublicense granting West
17 Therapeutic Development, LLC certain rights to develop and market Synacthen in the
18 United States.

19 **4. Mallinckrodt's Sales of Acthar to Humana and its Members**

20 83. Mallinckrodt has complete control over the price of Acthar and has on
21 many occasions increased its price without negotiating with any of the purchasers or
22 consumers of Acthar. Mallinckrodt is the sole entity with control over the wholesale
23 acquisition cost (WAC) of Acthar that determines the price at which Acthar is sold
24 throughout the pharmaceutical distribution chain. No other company has any influence
25 over the price of Acthar in the marketplace.

26 84. Humana is obligated to and does pay the price of Acthar that Mallinckrodt
27 sets. Mallinckrodt has purposefully sought to insulate itself from liability for the pricing
28 of Acthar by engaging its co-conspirator Express Scripts as an intermediary in the sale

1 of Acthar to all other purchasers. Express Scripts' CuraScript SD unit serves as the
2 exclusive distributor of Acthar. But CuraScript SD has no independent authority to set
3 the price of Acthar and bears no risk from Acthar sales. CuraScript bears no pricing risk
4 for Acthar because it is guaranteed an adjustment in its acquisition costs if Mallinckrodt
5 changes the price of Acthar. Furthermore, CuraScript is paid a fixed fee for each vial of
6 Acthar that is sold by Mallinckrodt (CuraScript SD does no marketing or selling of
7 Acthar) so it does not incur any benefit or cost based on the price of Acthar. In 2009
8 that fixed fee was set at \$230 per vial. CuraScript bears no risk of holding Acthar in
9 inventory because Mallinckrodt has agreed to accept returns of any Acthar which goes
10 unsold before its expiration date. With respect to sales of Acthar, CuraScript is
11 completely controlled by Mallinckrodt and acts merely as its agent.

12 85. In addition to dictating its actions through contractual terms, Mallinckrodt
13 confirmed that CuraScript SD was subject to its control by telling the SEC that if
14 CuraScript SD were to fail to perform in the way that it wished, it could quickly and
15 easily switch to a distributor who would provide "equivalent services." CuraScript SD
16 had no choice but to comply with Mallinckrodt's directives because it was at risk of
17 being terminated and replaced with a distributor that would. Furthermore, CuraScript
18 SD's parent, Express Scripts, had many other lucrative consulting, administrative
19 services, and specialty pharmacy sales arrangements with Mallinckrodt that would also
20 be at risk if CuraScript SD did not perform at Mallinckrodt's command. CuraScript SD
21 and its parent Express Scripts were not only complicit in, but actively took part in
22 Mallinckrodt's scheme to further its monopoly in the ACTH drug market. As a co-
23 conspirator and beneficiary of Mallinckrodt's scheme, there was no realistic possibility
24 that CuraScript SD or its parent Express Scripts would ever bring suit against
25 Mallinckrodt based on its anticompetitive actions.

26 86. Humana paid for almost \$800 million worth of Acthar during the relevant
27 period. Humana's Acthar purchases were made according to the wholesale cost that
28 Mallinckrodt set and controlled. Humana purchased Acthar from Mallinckrodt's agent

1 CuraScript SD and also from other specialty pharmacies that fulfilled prescriptions for
2 its members.

3 87. In 2015, Humana’s commercial insurance division directly contracted with
4 Mallinckrodt for rebates based on its Acthar purchases made for members of Humana’s
5 commercial insurance plans. In January 2017, Humana’s Medicare business entered
6 into a second rebate agreement with Mallinckrodt covering purchases made for
7 members on Humana’s Medicare plans. The claims and causes of action asserted in this
8 complaint do not arise out of or relate to those agreements, and Humana is not asserting
9 any claims or seeking any damages for breach of either of these agreements.

10 **5. Scope of the Antitrust Allegations**

11 88. Product Market. The relevant product market is long-acting ACTH drugs,
12 consisting of Acthar and Synacthen. During the relevant time period, Acthar was the
13 only long-acting ACTH drug approved by the FDA for sale in the United States.

14 89. Alternatively, long-acting ACTH drugs are a valid submarket within a
15 broader market for adrenal hormone drugs.

16 a. Public Recognition – Long-acting ACTH drugs are recognized by
17 Mallinckrodt, medical providers, and the public as differentiated from
18 other adrenal hormone drugs.

19 i. Acthar is publicly touted by Mallinckrodt as being “unique” and
20 facing limited competition from other drugs, including
21 corticosteroids. Additionally, medical providers and the public
22 generally view Acthar as distinct from other adrenal hormone drugs
23 such as corticosteroids. One basis for such a view may be that
24 certain medical researchers, mostly funded by Mallinckrodt, have
25 published studies that recognize long-acting ACTH drugs as
26 medically distinct from corticosteroids.

27 ii. The FTC recognized “ACTH drugs” as a relevant antitrust market
28 when evaluating Mallinckrodt’s acquisition of Synacthen. The FTC

1 alleged in its complaint against Mallinckrodt related to that
2 acquisition that Acthar had “a 100% share of the market for ACTH
3 drugs in the United States” because “[n]o other ACTH drug is FDA-
4 approved for therapeutic use.”

5 iii. Mallinckrodt’s predecessor identified Synacthen as a potential
6 competitive threat in its SEC filings before it licensed the rights to
7 sell that drug in the United States. Mallinckrodt has relied upon
8 studies using Synacthen to support its requests for certain label
9 indications to the FDA.

10 iv. The size of the long-acting ACTH drug market is significant relative
11 to total spending on adrenal hormone drugs. From 2011 through the
12 end of 2019, Humana and its members spent more than \$800 million
13 on Acthar. During that same period, Humana and its members spent
14 less than \$500 million on Glucocorticoid drugs and less than
15 \$35,000 on short-acting adrenocorticotrophic hormones.

16 b. Product characteristics and uses – Long-acting ACTH drugs’ composition
17 and method of action are distinct from other adrenal hormone drugs.

18 i. Long-acting ACTH drugs’ biological mechanism of action is distinct
19 from other drugs in that they stimulate the adrenal gland to produce
20 cortisol. Glucocorticoid drugs are synthetic forms of cortisol that do
21 not work through the adrenal gland.

22 ii. Long-acting ACTH drugs are believed by some medical providers to
23 be differentiated from other adrenal hormone drugs because of this
24 distinction in its biological method of action. Certain medical
25 research, sponsored by Mallinckrodt, also claim that Acthar achieves
26 superior results to corticosteroids and/or support differing effects of
27 Acthar on the body relative to corticosteroids.
28

1 c. Unique production facilities – Long-acting ACTH drugs are made in
2 different facilities and using different processes than other adrenal
3 hormone drugs.

4 i. Acthar is produced at only one facility in Prince Edward Island,
5 Canada. Acthar is produced using a complex, biologic process that
6 is difficult to replicate.

7 ii. Glucocorticoid drugs are synthesized by manufacturers of chemicals
8 for pharmaceuticals in a variety of facilities throughout the world.
9 These facilities are not equipped to produce Acthar, nor could they
10 be easily modified in order to do so.

11 d. Distinct Customers – Long-acting ACTH drug customers are distinct from
12 customers for other adrenal hormones.

13 i. Users of Acthar are distinct from users of other adrenal hormone
14 drugs because those drugs have either failed to treat their conditions,
15 or those drugs are contraindicated for that patient. Therefore
16 corticosteroid drugs are not a viable option for that patient.

17 ii. In some instances, Acthar is inappropriately prescribed as a result of
18 bribes paid to doctors (as described further below) for patients for
19 whom corticosteroids are an appropriate medical and economic
20 substitute. Absent the illegal bribe, Acthar would not be prescribed
21 for these patients, therefore any substitution between corticosteroids
22 and Acthar for this subset of patients was induced and would not
23 have occurred in a market absent this conduct.

24 iii. The FDA has instructed that Acthar be labeled as “having limited
25 therapeutic value in those conditions responsive to corticosteroid
26 therapy.” Humana limits approved use of Acthar (other than for
27 infantile spasms) under its policies to patients who have
28 “contraindications or intolerance to corticosteroids that are not

1 expected to also occur with” Acthar. Other insurers impose very
2 similar restrictions on Acthar’s use. Mallinckrodt acknowledges
3 that Acthar “may not be prescribed unless a clear benefit in efficacy
4 or safety is demonstrated or until alternatives have failed to provide
5 positive patient outcomes or are not well tolerated by the patient.”

6 iv. Synacthen is not offered for sale in the United States because of
7 Mallinckrodt’s anticompetitive conduct

8 e. Distinct Prices – Prices for long-acting ACTH drugs are distinct from
9 prices for other adrenal hormone drugs.

10 i. Acthar’s price is distinct from that of other adrenal hormone drugs.
11 Prices of drugs to payors, such as Humana, are the full cost of the
12 drug, less any portion of the cost for which the member is
13 responsible. Acthar’s price to Humana in 2019 averaged more than
14 \$65,000 per prescription, more than 650,000% of the average
15 prescription price for a glucocorticoid drug (\$9.79).

16 ii. Acthar’s price to patients in the form of co-insurance or co-
17 payments is substantially higher than the price for other adrenal
18 hormone drugs. For Medicare members, Humana’s co-insurance
19 amounts averaged approximately \$1,500 per Acthar prescription in
20 2019. Comparatively, the average Humana Medicare member co-
21 payment or co-insurance for a glucocorticoid prescription averaged
22 approximately \$3.93. Thus, Acthar’s “price” in the form of co-
23 insurance to Humana’s Medicare members in 2019 averaged
24 35,000% higher than the price for glucocorticoid drugs.

25 iii. Even if a Humana member’s co-payment were subsidized by a co-
26 payment charity (as described further below), the amount that
27 member was responsible for (their price) remained unchanged.
28

1 Assumption of payment by co-payment charities did not alter the
2 price of the drug in the market.

3 iv. Synacthen is not offered for sale in the United States because of
4 Mallinckrodt's anticompetitive conduct.

5 f. Sensitivity to price changes - Prices and quantities of long-acting ACTH
6 drugs are not sensitive to changes in prices of other adrenal hormone
7 drugs.

8 i. The price of Acthar has increased repeatedly and substantially while
9 the price of other Glucocorticoid drugs has decreased.

10 ii. The cross-price elasticity between Acthar and Glucocorticoid drugs
11 is extremely small. The cross-price elasticity between Acthar and
12 short-acting adrenocorticotrophic hormones is extremely small.

13 iii. The cross-price elasticity between Synacthen and Acthar is believed
14 to be highly significant (above 2.0).

15 iv. Synacthen is not offered for sale in the United States because of
16 Mallinckrodt's anticompetitive conduct

17 g. Distinct vendors - Long-acting ACTH drugs are sold by vendors that are
18 distinct from those that sell other adrenal hormone drugs.

19 i. Acthar is distributed only through a limited network of specialty
20 pharmacies (e.g. Accredo, BrivoRx, Senderra), while other adrenal
21 hormone drugs are widely available through tens of thousands of
22 retail and other mainstream pharmacies throughout the country (e.g.
23 CVS, Rite Aid, Walgreens). Acthar requires special handling that
24 retail pharmacies are not well equipped to provide.

25 ii. Synacthen is not offered for sale in the United States because of
26 Mallinckrodt's anticompetitive conduct.

27 90. Geographic Market. The relevant market is the entire United States.
28

1 91. Time. The relevant period is from 2011 through the present. Humana
2 specifically alleges that the conduct and patterns of conduct alleged here occurred and
3 continued to occur throughout this period.

4 **E. Mallinckrodt’s Kickback and Racketeering Schemes**

5 92. Mallinckrodt designed and coordinated a multifaceted scheme (the “Acthar
6 Enterprise”) intended to charge and maintain inflated prices for Acthar, including
7 through a conspiracy to defraud payors such as Humana. Built on Mallinckrodt’s
8 monopolistic practices, the scheme consisted of two subsidiary schemes: (1) illicit
9 patient co-pay subsidies through sham charitable funds; and (2) kickbacks to the
10 Prescribing Doctors.

11 **1. Patient Co-Pay Subsidies Through Sham Charitable Funds**

12 93. Not long after raising Acthar’s price to over \$23,000 per vial in 2007,
13 Questcor knew that it might have priced itself out of the MS market. Questcor also
14 understood that, for some insurance plans, the over-\$23,000 price could lead to very
15 high patient costs. Medicare Part D beneficiaries, in particular, could owe thousands of
16 dollars in co-pays for one vial of Acthar.

17 94. Questcor realized that it could overcome doctor and patient cost concerns
18 by subsidizing patient co-pay obligations, and thereby defrauding Medicare Part D
19 payors like Humana. Questcor knew that it was illegal to subsidize Medicare co-pays
20 directly, so it sought to accomplish the same result through a “co-pay assistance fund”
21 that it designed, created, and used as a money conduit to pay patient co-pay subsidies
22 for Acthar (but no other drug).

23 95. The operation was spearheaded by the executives of Questcor and aided by
24 the BioSolutia Consultant, who was retained full-time specifically for the purpose of
25 assisting with Acthar reimbursement.

26 96. By the spring of 2010, Questcor had tried one foundation (“NORD”) but
27 was dissatisfied with what it considered to be the small scale of the operation, and
28 looked instead for a foundation where it could fund co-pays on a much larger scale.

1 This effort resulted in Questcor connecting with CDF to discuss starting a new fund for
2 Questcor.

3 97. Though CDF already had a fund for MS patients, Questcor sought to
4 establish an “MS Exacerbation Co-pay Fund” distinct from CDF’s existing fund
5 because Questcor did not want to make payments to a fund that might pay the co-pays
6 of MS drugs other than Acthar.

7 98. After a presentation by CDF, Questcor moved its co-pay programs from
8 NORD to CDF. Questcor and CDF established a new “MS Acute Exacerbation Fund”
9 just for patients with government insurance, such as Medicare Part D, and just for the
10 co-pays of Acthar but no other drugs. For patients with private insurance, Questcor had
11 CDF open a separate Acthar “Private Fund” for Mallinckrodt to send private insurance
12 patients to CDF to have Acthar co-pays paid. That fund also exclusively covered Acthar
13 and Questcor financed that fund. Questcor’s donation agreement falsely represented
14 that the funds were generally for treatment of patients with acute exacerbations of MS,
15 when in fact Questcor knew it was just for patients using Acthar. Questcor thereafter
16 made co-pay assistance an important part of its sales and marketing program.

17 99. Questcor sent patients to CDF through Questcor’s “reimbursement hub”
18 for Acthar, called the Acthar Support and Access Program (“ASAP”), which was
19 administered by UBC under Mallinckrodt’s direction and control. Questcor and UBC
20 controlled ASAP, which included a call center that received referrals for Acthar from
21 physician offices and patients. Questcor’s sales force took steps to ensure that any
22 Acthar prescriptions were routed through ASAP so that Questcor could track them.
23 Patients sometimes had their co-pays paid for months or years through the fund.

24 100. In 2011, Questcor repeated this scheme in connection with a “Lupus
25 Exacerbation” fund. Questcor financed the fund. It falsely stated that the fund was for
26 “any medically appropriate therapy,” when in fact Questcor intended to fund only
27 Acthar and exclude other therapies. Questcor and UBC referred patients to the fund
28 through ASAP and tracked the patients thereafter. And through 2014, the Lupus

1 Exacerbation fund paid the co-pays of Acthar but no other drug, again often for months
2 or years.

3 101. In 2012, Questcor repeated the scheme yet again for rheumatoid arthritis
4 patients. It created an “RA Exacerbation Fund” at CDF, financed the fund, sent patients
5 to the fund through ASAP with UBC’s assistance, tracked the patients, and paid
6 subsidies for sometimes months’ or years’ worth of refills of Acthar but no other drug.

7 102. That same year, Questcor became concerned that it would lose referrals to
8 the fund for lack of co-pay assistance. Questcor therefore implemented an “automatic
9 offering” of co-pay assistance to all patients with co-pays greater than \$150,
10 administered by UBC through the reimbursement hub. The ASAP program referred
11 over 98 percent of the patients who received co-pay subsidies from the MS, Lupus, or
12 RA Exacerbation funds at CDF.

13 103. During the same period that Questcor sent Acthar patients to CDF to
14 receive Medicare co-pay subsidies, Questcor also retained NORD to operate a “Patient
15 Assistance Program” (“PAP”) that offered free Acthar to patients who met certain
16 financial criteria and could not afford the drug’s high price. ASAP also sent certain
17 patients to NORD for that purpose. As with ASAP, the PAP program was administered
18 by UBC under Mallinckrodt’s direction and control. But Questcor intentionally did not
19 send Acthar patients with Medicare or other insurance coverage for the drug to the
20 NORD PAP. Instead, Questcor sent those patients to CDF, where they received co-pay
21 subsidies to cover their costs and triggered insurance reimbursement for Acthar.

22 Questcor also required patients to appeal insurance coverage denials of Acthar before
23 referring them to the PAP. In other words, whenever possible, Mallinckrodt sought to
24 cause Medicare claims to be submitted for Acthar so that Mallinckrodt could get paid
25 from a sale of the drug as opposed to giving it away for free through the NORD PAP.

26 104. Questcor marketed guaranteed co-pay assistance to physicians and patients
27 as a way to neutralize concerns about the price and to induce sales and Medicare
28 reimbursement. This began immediately after establishing the MS Acute Exacerbation

1 Fund at CDF and continued throughout the relevant time period. For example, company
2 training materials instructed the sales force: “DO NOT APOLOGIZE FOR THE
3 PRICE.” The training instead directed sales representatives to “[r]eview [the] co-pay
4 coverage program” with prescribers who expressed concern about the drug’s price.

5 105. Furthermore, after Questcor conducted research and discovered that price
6 was an obstacle to more prescriptions, Questcor’s internal remediation plan noted the
7 importance of co-pay support.

8 106. Questcor’s sales force continued to promote guaranteed Acthar co-pay
9 subsidies through CDF in this manner, with the intent to induce Medicare Part D
10 claims.

11 107. Questcor monitored its co-pay support programs by receiving detailed
12 financial reports from CDF containing information about how many patients were
13 enrolled in the fund, how much the fund had already paid out, and how much had been
14 allocated to enrolled patients. The reports also stated the percentage of patients
15 approved to receive co-pay subsidies, the average co-pay amount paid by the fund, the
16 total number of resulting drug “dispenses” (broken out by new dispenses vs. refills),
17 and the remaining fund balance. Because these funds paid Acthar co-pays only, all of
18 these reported metrics were specific to Acthar. This gave Questcor the ability to
19 monitor its fund balances and confirm the amount of future payments to CDF necessary
20 to keep paying Acthar co-pay subsidies smoothly.

21 108. The funds worked as planned. After Questcor established the co-pay
22 conduit at CDF, Questcor achieved significant growth in Acthar MS sales and corporate
23 revenue. For example, Acthar MS sales nearly quadrupled between the third quarter of
24 2010 (when Questcor established the MS “acute exacerbation” fund) and the third
25 quarter of 2013.

26 109. Questcor also intensified its dramatic price increases. On January 3, 2011
27 Questcor raised Acthar’s price to over \$24,430 per vial. Under six months later, it
28 raised the price again to over \$25,600 per vial. In December 2011, it raised the price to

1 over \$27,300 per vial. In May 2012, it raised the price to over \$28,680 per vial. In June
2 2013, it raised the price to over \$30,100 per vial. In January 2014, it raised the price to
3 over \$31,600 per vial. In December 2014 it raised the price to over \$32,200 per vial.

4 110. The Company knowingly and willfully violated the federal Anti-Kickback
5 Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), by paying illegal Acthar co-pay subsidies as
6 described above to induce prescriptions and sales of Acthar reimbursed by Medicare,
7 and knowingly and willfully violated the False Claims Act (“FCA”), 31 U.S.C. §§
8 3729-3733, and its prohibition on submitting, or causing to be submitted, false claims to
9 federal health care programs, including Medicare. The Company’s knowledge and
10 willfulness is evidenced by internal training materials that instructed its employees on
11 these laws and their relevant prohibitions; corporate policies reflecting the Company’s
12 knowledge of its illegality; trade publications and articles circulated among the key
13 executives and consultants warning against the practice; and longstanding and repeated
14 warnings about the practice from the Office of the Inspector General of the United
15 States Department of Health and Human Services.

16 111. On information and belief, Mallinckrodt continued to pay or substantially
17 subsidize required patient co-payments for Acthar after 2014 and continues to do so
18 until today.⁸

19 **2. Physician Kickbacks**

20 112. The second part of the Acthar Enterprise consisted of kickbacks to the
21 Prescribing Doctors in exchange for increased prescriptions of Acthar.

22 113. Mallinckrodt’s co-pay subsidies were one way to prop up demand and
23 receive payment from third-party payors such as Humana. Another was Mallinckrodt’s
24 aggressive push to move away from prescriptions for infantile spasms and towards
25 conditions affecting elderly patients, and therefore to increase reimbursement by

26
27 ⁸ Mallinckrodt, “Acthar Reimbursement and Copayment Support,”
28 <https://www.actharishcp.com/reimbursement-and-copay> (last visited August 4, 2019).

1 Medicare and third-party payors like Humana. Mallinckrodt has heavily marketed
2 Acthar to neurologists (for MS), to nephrologists (for idiopathic membranous
3 nephropathy and nephrotic syndrome), to rheumatologists (for a variety of conditions
4 including rheumatoid arthritis), to pulmonologists (for sarcoidosis), and to
5 ophthalmologists (for severe allergic or inflammatory eye conditions).

6 114. In 2014 the president of the autoimmune and rare-disease business selling
7 Acthar made a presentation to investors detailing a strategy to expand Acthar's sales to
8 patients in rheumatology, pulmonology, ophthalmology, dermatology, and kidney
9 disease. In the several decades prior, Acthar had not been prescribed in large quantities
10 for these conditions despite having been FDA approved for such treatments. Although
11 there were no new medical studies suggesting Acthar was needed to treat any of these
12 conditions, the president pledged to "expand significantly" Acthar's sales force in the
13 fields of rheumatology and pulmonology in the upcoming year. That sales effort was
14 wildly successful at expanding the market for Acthar beyond infantile spasms. Now
15 fewer than 10% of Acthar's sales come from prescriptions for infantile spasms, and
16 more than 98% of Humana's expenditures for Acthar were made for insureds over the
17 age of 18.

18 115. A 2018 study published in JAMA Network Open concluded that
19 "[a]ggressive sales tactics and payments from [Mallinckrodt] may influence prescribing
20 behavior for [Acthar]." Indeed their "findings suggest that financial conflicts of interest
21 may be driving use of corticotropin in the Medicare program." The study examined
22 Medicare data about the providers who submitted more than ten claims for Acthar. It
23 noted that "[a]mong the 50 prescribers (21.3%) who received more than \$10 000 in
24 payments during the year [2015], corticotropin expenditures per prescriber (mean [SD],
25 \$1 304 884 [\$1 022 937]) were more than double that of the 45 prescribers (19.2%)
26 who received \$25 or less (mean [SD], \$594 976 [\$256 357])." The study's invariable
27 regression analysis further showed that "Medicare spending on [Acthar] increased by
28 7.9% (approximately \$53 000) for every \$10 000 increase in payments to prescribers,"

1 or a return of investment of approximately 5:1. The study further noted that 207 of 235
2 frequent corticotropin prescribers (88%) who submitted more than 10 claims received a
3 corticotropin-related payment from Mallinckrodt. By contrast, a recent study found that
4 among all specialists, only 35% receive payments from the pharmaceutical industry.

5 116. From 2013 to 2016, Mallinckrodt paid doctors nearly \$27.5 million in
6 Acthar-related payments. A handful of doctors received unusually large sums of money:
7 during the same period, Mallinckrodt paid more than \$6.5 million to only 288
8 prescribers for consulting, promotional speaking, and other services related to Acthar.

9 117. Many of the top prescribers to Humana's members have been paid
10 substantial fees by Mallinckrodt. These include the following:

Prescribing Doctor	Specialty	Amount Paid By Mallinckrodt to the Prescribing Doctor (Payment Dates)	Amount Humana Paid for Acthar Prescriptions by These Doctors
1	Int. Med./Sarcoidosis	\$116,000 (2013-2015)	\$10,672,325
2	Rheumatology	\$22,762 (2013-2015)	\$4,841,709
3	Rheumatology	\$273,937 (2013-2016)	\$3,459,480
4	Neurology	\$142,978 (2013)	\$2,723,683
5	Rheumatology	\$267,701 (2013-2016)	\$1,928,838
6	Rheumatology	\$370,970 (2013-2016)	\$778,060
7	Psychiatry/Neurology	\$345,913 (2013-2016)	\$739,894
8	Rheumatology	\$224,713 (2013-2016)	\$612,561
9	Neurology	\$332,393 (2013-2016)	\$379,250

18 The goal of Mallinckrodt's scheme was to increase its sales of Acthar at the expense of
19 those who paid for it—primarily health insurers such as Humana. Mallinckrodt required
20 the assistance and complicity of the Prescribing Doctors to achieve its ends. It knew
21 that in order to increase the prescription rates of Acthar, the Prescribing Doctors would
22 need to prescribe Acthar in situations in which it was not called for and in lieu of
23 considerably more cost-effective medications.

24 118. On September 3, 2019, Mallinckrodt paid more than \$15 million to the
25 United States Department of Justice to settle claims that it paid illegal kickbacks to
26 doctors to prescribe Acthar.

1 **3. False Representations and Certifications**

2 119. In order to effectuate its scheme, Mallinckrodt either made or caused to be
3 made three kinds of false representations and certifications directly to Humana.

4 120. *First*, Mallinckrodt directly misrepresented to Humana that it was
5 complying with state and federal law, including laws related bribery, kickbacks, and
6 false claims.

7 121. When a pharmacy dispenses drugs to a Humana Part D member, the
8 pharmacy submits a claim to Humana, which in turn submits an electronic record of the
9 claim, called a Prescription Drug Event (“PDE”), to CMS. After dispensing the drug,
10 the pharmacy receives reimbursement from Humana for the portion of the drug cost not
11 paid by the Part D member at the point of sale.

12 122. PDE claims data are necessary for CMS to administer the Part D program
13 and to reimburse Part D Plan Sponsors such as Humana. Generating and submitting
14 PDE data is a condition of payment for CMS' provision of Medicare funds to Part D
15 Plan sponsors. *See* 42 C.F.R. § 423.322.

16 123. Part D Plan Sponsors must comply with “[f]ederal laws and regulations
17 designed to prevent fraud, waste, and abuse, including, but not limited to, applicable
18 provisions of Federal criminal law, the False Claims Act (31 U.S.C. § 3729, *et seq.*),
19 and the anti-kickback statute (§ 1127B(b)) of the Act).” 42 C.F.R. § 423.505(h)(1). Any
20 “downstream” or “related” entities that Part D Plans subcontract with (including
21 pharmacies dispensing medication and manufacturers selling medication) must also
22 comply with these, and any other, contractual obligations of the Part D Plan and with all
23 applicable federal laws, regulations, and CMS instructions. *See* 42 C.F.R. §
24 423.505(i)(3).

25 124. CMS regulations require Part D Plan Sponsors and related “downstream”
26 entities that generate and submit PDE claims data to certify that such data is true,
27 accurate, and complete and that the PDE data is the basis for obtaining federal
28 reimbursement for the health care products or services reflected therein. *Id.*

1 § 423.505(k). Congress has determined that any Medicare claim “that includes items or
2 services resulting from a violation of [the AKS] constitutes a false or fraudulent claim
3 for purposes of [the FCA].” 42 U.S.C. § 1320a-7b(g).

4 125. Mallinckrodt and its captive agent CuraScript made such certifications and
5 therefore directly misrepresented to Humana that they were complying with federal law.

6 126. *Second*, when providers, including the Prescribing Doctors, prescribe
7 pharmaceutical treatment, they must generally obtain prior authorization from insurers
8 such as Humana. By going through the prior authorization process, the Prescribing
9 Doctors represent to Humana that the prescription medication is medically necessary,
10 up-to-date, and non-duplicative. They are further representing that they are not violating
11 state or federal law applicable to the provision of their services.

12 127. Mallinckrodt, CDF, and the Prescribing Doctors knew that offering or
13 accepting money or other consideration in exchange for prescriptions was a violation of
14 the law and CMS policies and procedures. Mallinckrodt, CDF, and the Prescribing
15 Doctors knew that their enterprise was a violation of these rules because it involved a
16 payment in exchange for an increased rate of prescriptions.

17 128. Through its unlawful payments to the Prescribing Doctors and its
18 payments to patients through the CDF funds, Mallinckrodt caused false certifications
19 and representations to be made to Humana during the prior authorization process.

20 129. *Third*, Humana members are required to pay what they owe for drug
21 coverage under Medicare Part D and other kinds of plans, and they are advised in their
22 evidence of coverage documents that they must pay their share of the cost when they
23 obtain prescription drugs. Through its illegal scheme to pay patient co-pays through
24 phony charitable funds at CDF, Mallinckrodt caused Humana members to
25 unintentionally misrepresent that they had paid their contractual share of prescription
26 drug coverage.

1 **4. Use of the Mails and Wires**

2 130. Throughout the relevant period, Mallinckrodt, CDF, and the Prescribing
3 Doctors used thousands of mail and interstate wire communications to create and
4 manage their scheme, which involved nationwide distribution of Acthar through the
5 Prescribing Doctors and CuraScript at the direction of Mallinckrodt. Mallinckrodt
6 communicated with the Prescribing Doctors through the mails and wires, caused
7 thousands of reimbursement requests to be submitted by the Prescribing Doctors over
8 the wires or by mail, and made illegal kickback payments to the Prescribing Doctors
9 over the wires or by mail.

10 **F. Mallinckrodt's Fraudulent Concealment of the Illegal Scheme**

11 131. Mallinckrodt actively concealed the existence of its illegal scheme and the
12 acts underlying it through false or misleading statements to Humana and to the public.
13 Mallinckrodt falsely maintained that it would develop and seek FDA approval of
14 Synacthen when in reality it purposefully failed to put the effort and resources into
15 obtaining a broad FDA approval of Synacthen as an alternative to Acthar. Mallinckrodt
16 also failed to disclose to Humana its arrangements with CDF that created specialized
17 funds that were used to illegally reimburse co-payments for Acthar, despite its
18 certifications to Humana that it was following federal law and CMS rules that
19 prohibited such co-payment subsidies for Medicare patients. Finally, Mallinckrodt also
20 failed to disclose its kickback payments to doctors that violated federal law and CMS
21 rules despite its certifications to Humana that it was abiding by such laws and CMS
22 rules.

23 132. Due to Mallinckrodt's fraudulent concealment, Humana could not have
24 discovered and remained unaware of the foregoing conduct until the Federal Trade
25 Commission and the United States Department of Justice brought these acts and
26 practices to light through investigations, legal actions, and/or settlements.

G. Damages

133. As a result of Mallinckrodt's multipronged scheme to inflate Acthar's price and utilization, Humana incurred significant losses. A substantial portion of Humana's business is evaluating, underwriting, and managing risks involved in insuring healthcare costs. As a commercial insurer, Humana bears significant risk of utilization of unnecessary, ineffective, or uneconomical medical care. The same is true for Humana's Medicare plans.

134. For Humana's Medicare business, Humana bears the risk of rising prescription drug prices and utilization in part through Part D "risk corridors" and Medicare Advantage capitation payments. Both of these Medicare provisions shift risk from the federal government to Humana to pay for some or all of the increased costs of prescription drugs for the Medicare members it covers. As such, Humana benefits financially when costs and utilization of prescription drugs are lower than expected and conversely it is harmed when costs and utilization of prescription drugs are higher than expected. In addition, for the portion of costs covered by the government under these programs, Humana bears a risk of non-payment if claims are found to be false or fraudulent by the government.

135. The risk of fraudulent claims is one that is shared by Humana and the government sponsors of healthcare plans that Humana administers. Therefore the claims of the government and the claims of Humana against Mallinckrodt are substantially the same.

136. Mallinckrodt's scheme was designed to cause and did cause Humana and others to pay for Acthar prescriptions that they would otherwise not have reimbursed and to pay more for those prescriptions than they otherwise would have paid. Humana was among the group of health insurers who were the targets of Mallinckrodt's scheme. Mallinckrodt knew that nearly all of its sales of Acthar in the United States would be sold to patients who carried prescription drug insurance that would bear the majority of

1 Acthar's cost. Humana's insurance plans bore the majority of Acthar's costs for its
2 members and was directly injured as a result of Mallinckrodt's illegal conduct.

3 137. But for Mallinckrodt's scheme to perpetuate its monopoly over long-acting
4 ACTH drugs, illegally subsidize Humana's members' co-pays, and pay kickbacks to
5 Prescribing Doctors, Humana would have paid for fewer Acthar prescriptions and it
6 would have paid less for those prescriptions that it otherwise would have covered.
7 Specifically, but for Mallinckrodt's monopolistic conduct, including its acquisition of
8 Synacthen, Humana would have benefitted from increased competition in the market
9 for long-acting ACTH drugs and would have either paid lower prices for Acthar or it
10 would have steered its members to lower priced Synacthen. Similarly, but for
11 Mallinckrodt's kickbacks, Mallinckrodt and the Prescribing Doctors would not have
12 defrauded Humana by falsely certifying their compliance with federal and state law
13 through submissions for reimbursements for Acthar prescriptions. Finally, but for
14 Mallinckrodt's kickback scheme and illegal co-pay assistance through CDF,
15 prescription rates for Acthar would have been lower, and Humana members would have
16 received different care from their physicians that was more effective, less harmful, or
17 more cost effective than doses of Acthar.

18 138. As a consequence of Mallinckrodt's conduct, Humana paid almost \$800
19 million for Acthar prescriptions. In the absence of such conduct, Humana would have
20 paid a small fraction of that amount. Humana has also incurred administrative,
21 investigative, legal, and other costs as a result of Mallinckrodt's conduct.

22 **Count I**

23 **Violation of the Sherman Antitrust Act, 15 U.S.C. § 2**

24 139. Humana incorporates by reference each of the above paragraphs of this
25 Complaint as though fully stated herein.

26 140. Mallinckrodt has, and at all relevant times, had monopoly power in the
27 market for the sale of long-acting ACTH drugs in the United States.
28

1 141. By intervening in the bidding process for Synacthen and purchasing the
2 exclusive license to market Synacthen in the United States, Mallinckrodt eliminated the
3 potential competitive threat posed by an independently owned Synacthen license.
4 Mallinckrodt's conduct was reasonably capable of contributing significantly to the
5 preservation of Mallinckrodt's monopoly power and monopoly pricing of Acthar in the
6 United States.

7 142. The effect of Mallinckrodt's actions to maintain its monopoly was to
8 stabilize or raise the price of Acthar to a higher level than it would have commanded in
9 the absence of the monopolistic conduct. Mallinckrodt's actions also had the effect of
10 suppressing the output of long-acting ACTH drugs below the level of output which
11 would have been produced absent its monopolistic conduct.

12 143. Humana suffered injuries when it paid those higher prices.

13 144. Defendant's acts and practices constitute monopolization in violation of
14 Section 2 of the Sherman Act, 15 U.S.C. § 2.

15 **Count II**

16 **Violation of the Sherman Antitrust Act, 15 U.S.C. § 1**

17 145. Humana incorporates by reference each of the above paragraphs of this
18 Complaint as though fully stated herein.

19 146. Mallinckrodt entered into an exclusive agreement with Novartis to license
20 the right to market Synacthen in the United States.

21 147. That agreement restrained trade in the market for the sale of long-acting
22 ACTH drugs in the United States.

23 148. The effect of that agreement was to maintain or raise the price of Acthar to
24 a higher level than it would have commanded in the absence of the agreement and to
25 suppress the output of long-acting ACTH drugs below that which would have prevailed
26 in the absence of the agreement.

27 149. Humana suffered injuries when it paid those higher prices.

28

Violation of State Antitrust Laws

152. The aforementioned practices by the Defendant that violate Sections 1 and 2 of the Sherman Act were and are also violations of the following states' antitrust laws:

- A-7202**

- s. N.C. Gen. Stat. § 75-1, *et seq.* (North Carolina);
- t. Or. Rev. Stat. Ann. § 646.705, *et seq.* (Oregon);
- u. S.D. Codified Laws § 37-1-3.1, *et seq.* (South Dakota);
- v. Tenn. Code Ann. § 47-25-101, *et seq.* (Tennessee);
- w. Utah Code Ann. § 76-10-3101, *et seq.* (Utah);
- x. Vt. Stat. Ann. tit. 9, § 2451, *et seq.* (Vermont);
- y. Wis. Stat. Ann. § 133.01, *et seq.* (Wisconsin).

Count IV

Violation of the RICO Act, 18 U.S.C. § 1962(c)

153. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

154. Mallinckrodt is a “person” within the meaning of 18 U.S.C. § 1961(3), who conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

155. The Acthar Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Mallinckrodt, Express Scripts and its relevant subsidiaries (including CuraScript), CDF, and the Prescribing Doctors—including their corporate parents, siblings, subsidiaries, employees, and agents. The Acthar Enterprise was an ongoing organization that functioned as a continuing unit. The Acthar Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Mallinckrodt, Express Scripts, CuraScript, CDF, and the Prescribing Doctors are each “persons” distinct from the Acthar Enterprise.

156. Mallinckrodt established the Acthar Enterprise to fraudulently increase its sales of Acthar. Mallinckrodt subsidized co-pays through CDF, and paid the Prescribing Doctors, in exchange for an increased rate of prescriptions of Acthar in lieu of less expensive alternative treatment. Mallinckrodt, CDF, and the Prescribing Doctors knew that their scheme violated federal and state laws.

1 157. Such payments also violated state commercial bribery statutes which
2 prohibit offering anything of value to a fiduciary for the purpose of altering the
3 fiduciary's conduct towards those to whom he owes fiduciary duties. Doctors, like the
4 Prescribing Doctors, owe fiduciary duties to their patients to offer medical advice and
5 counseling based on the best interest of the patient, not what is in their own pecuniary
6 interest.

7 158. False representations of compliance with federal and state laws were made
8 to Humana for payment over the wires or by mail. These false representations were
9 made directly to Humana and were a condition of reimbursement by Humana for all
10 Acthar claims submitted by the Prescribing Doctors. The illegal payments were sent
11 over the wires or by mail to the Prescribing Doctors and to CDF.

12 159. The Acthar Enterprise engaged in and affected interstate commerce
13 because, among other things, it marketed, sold, purchased, or provided Acthar to
14 thousands of individuals throughout the United States.

15 160. Mallinckrodt has asserted control over the Acthar Enterprise by issuing
16 payments to doctors who prescribed Acthar as treatment for conditions for which more
17 affordable alternative treatments were readily available. Mallinckrodt asserted control
18 over the enterprise by utilizing one exclusive distributor, CuraScript, and setting the
19 price of Acthar paid by Humana.

20 161. Mallinckrodt has asserted control over the Acthar Enterprise by designing,
21 organizing, and funding the phony charitable funds at CDF used for Acthar co-pays.

22 162. Mallinckrodt has conducted and participated in the affairs of the Acthar
23 Enterprise through a pattern of racketeering activity that includes acts indictable under
24 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), 1952 (use of interstate facilities to
25 conduct unlawful activity), and state bribery statutes.

26 163. The effect of Mallinckrodt's racketeering activity was to induce sales of
27 Acthar that otherwise would not have been made in the absence of the illegal conduct
28

1 and to maintain or raise the price of Acthar to a higher level than it would have
2 commanded in the absence of the illegal conduct.

3 164. Humana suffered injuries when it reimbursed those prescriptions for
4 Acthar that otherwise would not have been made and/or paid the higher prices that
5 resulted from the illegal conduct.

6 165. Humana's injuries were directly and proximately caused by Mallinckrodt's
7 racketeering activities as described above.

8 166. By virtue of these violations of 18 U.S.C. § 1962(c), Mallinckrodt is
9 jointly and severally liable to Humana for three times the damages Humana has
10 sustained, plus the cost of this suit, including reasonable attorneys' fees.

11 **Count V**

12 **Conspiracy to Violate the RICO Act, 18 U.S.C. § 1962(d)**

13 167. Humana incorporates by reference each of the above paragraphs of this
14 Complaint as though fully stated herein.

15 168. Title 18 U.S.C. § 1962(d) provides that it "shall be unlawful for any person
16 to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

17 169. Mallinckrodt has violated 18 U.S.C. § 1962(d) by conspiring with the
18 Prescribing Doctors, CuraScript, and CDF to violate 18 U.S.C. §1962(c). The object of
19 this conspiracy has been and is to conduct or participate in, directly or indirectly, the
20 conduct of the affairs of the Acthar Enterprise described previously through a pattern of
21 racketeering activity.

22 170. Mallinckrodt and its co-conspirators have engaged in numerous overt and
23 predicate fraudulent racketeering acts in furtherance of the conspiracy, including
24 material misrepresentations and omissions designed to defraud Humana of money.

25 171. The nature of the above-described Mallinckrodt's co-conspirators' acts,
26 material misrepresentations, and omissions in furtherance of the conspiracy gives rise to
27 an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d)
28 violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware

1 that their ongoing fraudulent and extortionate acts have been and are part of an overall
2 pattern of racketeering activity.

3 172. As a direct and proximate result of Mallinckrodt's overt acts and predicate
4 acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C.
5 § 1962(c), Humana has been injured in its business and property as set forth more fully
6 above.

7 173. Mallinckrodt and its co-conspirators have sought to and have engaged in
8 the commission of overt acts, including the following unlawful racketeering predicate
9 acts:

- 10 a. Multiple instances of mail and wire fraud in violation of 18 U.S.C. §§
11 1341 and 1342;
- 12 b. Multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and
13 1346;
- 14 c. Multiple instances of wire fraud in violation of 18 U.S.C. §§ 1343 and
15 1346;
- 16 d. Multiple instances of unlawful activity in violation of 18 U.S.C. §1952;
- 17 e. Multiple instances of bribery in violation of state statutes, including but
18 not limited to Cal. Penal Code § 641.3, 720 Ill. Comp. Stat. 5/29A-1,
19 Tex. Penal Code § 32.43, N.J. Stat. § 2C:21-10, and N.Y. Penal Law §
20 180.00.

21 174. The purpose and effect of the conspiracy was to induce sales of Acthar that
22 otherwise would not have been made in the absence of the illegal conduct and to
23 maintain or raise the price of Acthar to a higher level than it would have commanded in
24 the absence of the illegal conduct.

25 175. Humana suffered injuries when it reimbursed those prescriptions for
26 Acthar that otherwise would not have been made and/or paid the higher prices that
27 resulted from the illegal, conspiratorial conduct.
28

1 176. Humana's injuries were directly and proximately caused by Mallinckrodt's
2 racketeering activities as described above.

3 177. By virtue of these violations of 18 U.S.C. § 1962(d), Mallinckrodt is
4 jointly and severally liable to Humana for three times the damages Humana has
5 sustained, plus the cost of this suit, including reasonable attorneys' fees.

6 **Count VI**

7 **State Unfair Competition Law Claims**

8 178. Humana incorporates by reference each of the above paragraphs of this
9 Complaint as though fully stated herein.

10 179. Mallinckrodt and its co-conspirators have engaged in fraudulent and
11 deceptive business practices that violate the state unfair competition laws of Alaska,
12 Arizona, Arkansas, California, Connecticut, Florida, Idaho, Illinois, Indiana, Louisiana,
13 Maryland, Massachusetts, Michigan, Nebraska, New Hampshire, New Jersey, New
14 Mexico, North Carolina, North Dakota, Oregon, South Carolina, Tennessee,
15 Washington, Wisconsin, and Wyoming.

16 180. Mallinckrodt and its co-conspirators have engaged in unfair competition
17 under the states' laws by unlawfully making and accepting remuneration in exchange
18 for the sale of Acthar to Humana and its members in consumer transactions. This
19 conduct violated the federal AKS and equivalent state statutes and caused the
20 certifications of compliance with law provided by the Prescribing Doctors to Humana to
21 be fraudulent.

22 181. Plaintiff Humana was directly and proximately injured by Mallinckrodt
23 and its co-conspirators' conduct and would not have paid what it did for Acthar had
24 Mallinckrodt fully disclosed its schemes.

25 182. Mallinckrodt engaged in wrongful conduct while at the same time
26 obtaining under false pretenses a significant sum of money from plaintiff Humana.
27 Humana suffered injury in fact and actual damages including lost money and property
28 as a result of Mallinckrodt's violations of:

- a. A.S. § 45.50.471(a), *et seq.* (Alaska);
- b. Ariz. Rev. Stat. Ann. § 44-1521, *et seq.* (Arizona);
- c. Ark. Code Ann. § 4-88-101, *et seq.* (Arkansas);
- d. Cal. Bus. & Prof. Code § 17200, *et seq.* (California);
- e. Conn. Gen. Stat. § 42-110a, *et seq.* (Connecticut);
- f. Fla. Stat. § 501.201, *et seq.* (Florida);
- g. Idaho Code Ann. § 48-601, *et seq.* (Idaho);
- h. 815 Ill. Comp. Stat. 505/1, *et seq.* (Illinois);
- i. Ind. Code § 24-5-0.5-1, *et seq.* (Indiana);
- j. La. Rev. Stat. Ann. § 51:1401, *et seq.* (Louisiana);
- k. Md. Code Ann., Com. Law § 13-101, *et seq.* (Maryland);
- l. Mass. Gen. Laws Ann. ch. 93A, § 1, *et seq.* (Massachusetts);
- m. Mich. Comp. Laws § 445.901, *et seq.* (Michigan);
- n. Neb. Rev. Stat. § 59-1601, *et seq.* (Nebraska);
- o. N.H. Rev. Stat. Ann. § 358-A:1, *et seq.* (New Hampshire);
- p. N.J. Stat. Ann. § 56:8-1, *et seq.* (New Jersey);
- q. N.M. Stat. § 57-12-1, *et seq.* (New Mexico);
- r. N.C. Gen. Stat. § 75-1.1, *et seq.* (North Carolina);
- s. N.D. Cent. Code § 51-15-01, *et seq.* (North Dakota);
- t. O.R.S. 646.607, *et seq.* (Oregon);
- u. S.C. Code Ann. § 39-5-10, *et seq.* (South Carolina);
- v. Tenn. Code Ann. § 47-18-101, *et seq.* (Tennessee);
- w. Wash. Rev. Code § 19.86.010, *et seq.* (Washington);
- x. Wis. Stat. § 100.18, *et seq.* (Wisconsin);
- y. Wyo. Stat. Ann. § 40-12-101, *et seq.* (Wyoming).

183. Pursuant to these states' laws, Humana seeks judgment in its favor and against Mallinckrodt requiring Mallinckrodt to pay restitution of wrongful profits, revenues, and benefits received as a result of the Acthar schemes.

Count VII

State Consumer Fraud and Deceptive Trade Practice Law Claims

184. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

185. Mallinckrodt and its co-conspirators have engaged in fraudulent and deceptive business practices that violate the state consumer fraud, consumer protection, and/or deceptive trade practices laws of Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, North Carolina, South Carolina, Tennessee, and Wisconsin, and in particular the following laws:

- a. Ariz. Rev. Stat. Ann. § 44-1521, *et seq.* (Arizona);
- b. Ark. Code Ann. § 4-88-101, *et seq.* (Arkansas);
- c. Cal. Bus. & Prof. Code § 17200, *et seq.* (California);
- d. Colo. Rev. Stat. § 6-1-101, *et seq.* (Colorado);
- e. Conn. Gen. Stat. § 42-110a, *et seq.* (Connecticut);
- f. Fla. Stat. § 501.201, *et seq.* (Florida);
- g. Ga. Code Ann. § 10-1-390, *et seq.* (Georgia);
- h. 815 Ill. Comp. Stat. 505/1, *et seq.* (Illinois);
- i. Ind. Code § 24-5-0.5-1, *et seq.* (Indiana);
- j. La. Rev. Stat. Ann. § 51:1401, *et seq.* (Louisiana);
- k. Md. Code Ann., Com. Law § 13-101, *et seq.* (Maryland);
- l. Mass. Gen. Laws Ann. ch. 93A, § 1, *et seq.* (Massachusetts);
- m. Mich. Comp. Laws § 445.901, *et seq.* (Michigan);
- n. Minn. Stat. § 325F.68, *et seq.* (Minnesota);
- o. Neb. Rev. Stat. § 59-1601, *et seq.* (Nebraska);
- p. Nev. Rev. Stat. § 41.600, *et seq.* (Nevada);
- q. N.H. Rev. Stat. Ann. § 358-A:1, *et seq.* (New Hampshire);
- r. N.C. Gen. Stat. § 75-1.1, *et seq.* (North Carolina);

1 s. S.C. Code Ann. § 39-5-10, *et seq.* (South Carolina);

2 t. Tenn. Code Ann. § 47-18-101, *et seq.* (Tennessee);

3 u. Wis. Stat. § 100.18, *et seq.* (Wisconsin).

4 186. Humana is a person or consumer entitled to protection under the foregoing
5 state laws.

6 187. Mallinckrodt directly misrepresented to Humana that it was complying
7 with federal and state laws, including laws against bribery, kickbacks, and false claims
8 to the government. In addition, through its payments to doctors, Mallinckrodt induced
9 the Prescribing Doctors to falsely certify to Humana through the prior authorization
10 process that they had not received any illegal kickbacks from manufacturers.

11 188. Mallinckrodt intended payors such as Humana to rely on these
12 certifications. The intention may be inferred by the very nature of the representation,
13 whose sole purpose is to procure payment for Acthar.

14 189. These representations and certifications were made in an effort by
15 Mallinckrodt to sell Acthar to the consuming public, and were addressed to the market
16 generally by having Acthar paid for at inflated prices by Medicare, Medicaid, and third-
17 party payors such as Humana. The ultimate consequence of this conduct is a significant
18 injury to the consuming public by, among other things, imposing additional costs on the
19 taxpaying public for Medicare, raising the cost of insurance, and obstructing the
20 availability of Acthar and its synthetic substitute to consumers.

21 190. Humana relied on these misrepresentations to its detriment, which were
22 material to its decision to pay for Acthar treatments.

23 191. Humana was directly and proximately injured by Mallinckrodt and its co-
24 conspirators' conduct, suffered an injury in fact, and suffered actual, ascertainable
25 damages. Humana would not have paid for Acthar, or would have paid only a small
26 fraction of the amount it actually did pay, had Mallinckrodt refrained from engineering
27 the false representations or otherwise disclosed its schemes.

28

1 192. Mallinckrodt's conduct offends established public policy and the public
2 interest, and is immoral, unethical, oppressive, unscrupulous, and substantially injurious
3 to consumers.

4 **Count VIII**

5 **State Insurance Fraud Claims**

6 193. Humana incorporates by reference each of the above paragraphs of this
7 Complaint as though fully stated herein.

8 194. Mallinckrodt and its co-conspirators have committed insurance fraud in
9 violation of the laws of Illinois, Kentucky, Pennsylvania, New Jersey, and Tennessee,
10 and in particular the following laws:

- 11 a. 720 ILCS 5/17-10.5(Illinois);
- 12 b. Ky. Rev. Stat. § 304.47-010, *et seq.* (Kentucky);
- 13 c. 18 Pa. Cons. Stat. Ann. § 4117 (Pennsylvania);
- 14 d. N.J. Stat. § 17:33A, *et seq.* (New Jersey);
- 15 e. Tenn. Code Ann. §§ 56-53-101 (Tennessee).

16 195. Mallinckrodt knowingly presented or caused to be presented to Humana
17 statements in support of claims for insurance benefits for Acthar that it knew contained
18 false and/or misleading information. Mallinckrodt knew and intended that by engaging
19 in its schemes to pay kickbacks to doctors and illegally subsidize co-payments through
20 phony charitable funds that misleading and/or false information would be submitted to
21 Humana and other Medicare payors in connection with insurance claims.

22 196. The statements of the co-conspirator doctors who prescribed Acthar and
23 the pharmacies who filled Acthar prescriptions to Humana were false because they
24 certified compliance with federal and state laws and regulations that were not, in fact,
25 complied with. Among the laws which the doctors and pharmacies were not in
26 compliance with were the anti-kickback statutes.

27 197. The compliance certifications were material to Humana's decision to
28 reimburse claims for Acthar that Mallinckrodt caused to be submitted. Had the

1 certification of compliance with federal and state laws and regulations been withheld or
2 corrected by the doctors or pharmacies, Humana would not to have paid these claims.

3 198. Humana's injuries were directly and proximately caused by the false or
4 misleading statements that Mallinckrodt made to it, or caused to be submitted to it, as
5 described above.

6 **Count IX**

7 **Tortious Interference with Contractual Relations**

8 199. Humana incorporates by reference each of the above paragraphs of this
9 Complaint as though fully stated herein.

10 200. Humana had valid and enforceable written contracts with each of its
11 members who were prescribed Acthar during the relevant period. These agreements
12 specify that members will pay their share of the costs for prescription drugs. The
13 purpose of this co-payment obligation is to provide an incentive to members to exercise
14 patient responsibility for health care costs, and so to help control health care and health
15 insurance costs on a larger scale.

16 201. This co-payment obligation was known to Mallinckrodt, not only because
17 this is how most medical insurance generally works but also because Medicare policy
18 documents are largely prescribed by federal law. CMS mandates that insurers use
19 approved language in their Medicare policy documents, including the pertinent
20 Evidence of Coverage ("EOC") document. Those materials are publicly available and
21 well known in the pharmaceutical industry.⁹ Humana adopts these materials as issued
22 by CMS for its own EOC documents.

23
24
25 ⁹ See, e.g., <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketingModelsStandardDocumentsandEducationalMaterial> (CMS website collecting
26 model EOC documents) and <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials> (model Part D
27 materials).
28

1 202. For example, attached as **Exhibit A** is an Evidence of Coverage from
2 Humana written for a 2014 California plan incorporating Medicare’s model language.
3 That document provides that an insured is “responsible for” copayments and “must pay
4 [their] share of the cost when [they] get [a] service or drug.” *Id.* at 153. With respect to
5 PAPs in particular, the coverage document states:

6
7 **2. When you get a drug through a patient assistance program offered**
8 **by a drug manufacturer**

9 Some members are enrolled in a patient assistance program offered by
10 a drug manufacturer that is outside the plan benefits. If you get any
11 drugs through a program offered by a drug manufacturer, you may pay
12 a copayment to the patient assistance program.

- 13 • Save your receipt and send a copy to us so that we can have your
14 out-of-pocket expenses count toward qualifying you for the
15 Catastrophic Coverage Stage.
- 16 • **Please note:** Because you are getting your drug through the patient
17 assistance program and not through the plan's benefits, we will not
18 pay for any share of these drug costs. But sending a copy of the
19 receipt allows us to calculate your out-of-pocket costs correctly and
20 may help you qualify for the Catastrophic Coverage Stage more
21 quickly.

22 *Id.* at 141 (highlighting added); *see also id.* at 122 (advising members to provide
23 receipts for their co-pays to PAPs to “[m]ake sure that we have that information we
24 need” when the member “made a copayment for drugs that are provided under a drug
25 manufacturer patient assistance program”).

26 203. As the highlighted language makes plain to members, Humana does not
27 pay for drugs provided through a PAP, but the member’s expenses may affect the
28 computation of that member’s out-of-pocket costs. If the PAP uses its funds to pay the
member’s co-pay, however, then both the letter and the purpose of the EOC provision
are subverted. Mallinckrodt’s scheme to pay those patient co-pays through the sham
charitable funds at CDF did precisely that, causing members to unintentionally

1 represent that were paying their share of a covered drug when in fact they were not
2 paying and the drug was not covered.

3 204. Mallinckrodt intended to and did induce Humana members to breach their
4 obligations by subsidizing their co-pays.

5 205. Humana was harmed by these breaches because it reimbursed claims for
6 Acthar that otherwise would not have been made.

7 206. Mallinckrodt has intentionally interfered with the contracts between
8 Humana and its members.

9 207. Humana seeks judgment in its favor and against Mallinckrodt, requiring
10 Mallinckrodt to pay monetary and punitive damages for the conduct described herein.

11 **Count X**

12 **Unjust Enrichment**

13 208. Humana incorporates by reference each of the above paragraphs of this
14 Complaint as though fully stated herein.

15 209. As the intended and expected result of their conscious wrongdoing as set
16 forth in this Complaint, Mallinckrodt has profited and benefited from payments
17 Humana made for Acthar as a result of its schemes.

18 210. The circumstances of Mallinckrodt's receipt of monies based on the
19 conduct set forth in this Complaint are such that, in equity and good conscience,
20 Mallinckrodt should not retain such monies, the amount of which is to be determined at
21 trial.

22 211. Humana is entitled in equity to seek restitution of Mallinckrodt's wrongful
23 profits, revenues, and benefits received as a result of its schemes.

24 212. Humana states this claim to the extent that it is deemed not to have an
25 adequate legal remedy.

26 **V. PRAYER FOR RELIEF**

27 213. Based on the foregoing, Humana requests that the Court enter an order
28 that:

- a. Enters judgment in favor of Humana and against the Defendant;
- b. Awards Humana its actual damages in an amount to be determined at trial;
- c. Awards Humana punitive damages;
- d. Awards Humana treble damages under 15 U.S.C. § 15(a), 18 U.S.C. § 1964(c), or any other provision of law, including state law, that permits doubling or trebling of damages;
- e. Awards Humana its attorneys' fees and litigation costs under 15 U.S.C. § 15(a), 18 U.S.C. § 1964(c), or any other provision of law, including state law, that permits recovery of such costs and fees;
- f. Awards Humana pre-and post-judgment interest; and
- g. Provides any other relief that the Court deems proper.

VI. JURY DEMAND

214. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on all issues so triable.

Dated: April 24, 2020

By: /s/ Scott C. Solberg

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#:1242

EXHIBIT A

2014 Evidence of Coverage

Humana®

Your 2014 Evidence of Coverage

We're sending you this 2014 plan benefit information as required by the Centers for Medicare & Medicaid Services (CMS).

This document provides complete details of coverage and plan benefits for 2014.

Did you know you can get plan-related information online?

Visit **Humana.com** and log in to MyHumana to:

- View your plan details
- Check if a provider is in-network
- Choose how you want to receive information

2014 Evidence of Coverage

Humana Gold Plus®

H0108-004 (HMO)

Fresno

Fresno, Kings and Madera counties



Humana®

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#:1246

January 1 - December 31, 2014

Evidence of Coverage:

Your Medicare Health Benefits and Services and Prescription Drug Coverage as a Member of Humana Gold Plus H0108-004 (HMO)

This booklet gives you the details about your Medicare health care and prescription drug coverage from January 1 - December 31, 2014. It explains how to get coverage for the health care services and prescription drugs you need.

This is an important legal document. Please keep it in a safe place.

This plan, Humana Gold Plus H0108-004 (HMO), is offered by HUMANA HEALTH PLAN OF CALIFORNIA, INC. (When this Evidence of Coverage says "we," "us," or "our," it means HUMANA HEALTH PLAN OF CALIFORNIA, INC. When it says "plan" or "our plan," it means Humana Gold Plus H0108-004 (HMO).)

Humana Gold Plus H0108-004 (HMO) is a Medicare Advantage HMO plan with a Medicare contract. Enrollment in this Humana plan depends on contract renewal.

This information is available for free in other languages. Please contact our Customer Care number at 1-800-457-4708 for additional information. (TTY users should call: 711). Hours are from 8 a.m. to 8 p.m. seven days a week from Oct. 1 - Feb. 14 and 8 a.m. to 8 p.m. Monday-Friday from Feb. 15 - Sept. 30. Customer Care also has free language interpreter services available for non-English speakers.

No se cobra por recibir esta información en otros idiomas. Para obtener más información, comuníquese con nuestro departamento de Atención al Cliente llamando al 1-800-457-4708. (Los usuarios de TTY deben llamar al: 711). El horario de atención es de 8 a.m. a 8 p.m., los siete días de la semana entre el 1 de octubre y el 14 de febrero, y de 8 a.m. a 8 p.m., de lunes a viernes entre el 15 de febrero y el 30 de septiembre. Además, el departamento de Atención al Cliente les proporciona servicios gratuitos de intérpretes de otros idiomas a los afiliados que no hablen inglés.

This information is available in a different format, including Braille, large print, and audio tapes. Please call Customer Care at the number listed above if you need plan information in another format.

Benefits, formulary, pharmacy network, premium, deductible, and/or copayments/coinsurance may change on January 1, 2015.

2014 Evidence of Coverage

Table of Contents

This list of chapters and page numbers is your starting point. For more help in finding information you need, go to the first page of a chapter. **You will find a detailed list of topics at the beginning of each chapter.**

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SECTION 1 Introduction

Section 1.1	You are enrolled in Humana Gold Plus H0108-004 (HMO), which is a Medicare HMO
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You are covered by Medicare, and you have chosen to get your Medicare health care and your prescription drug coverage through our plan, Humana Gold Plus H0108-004 (HMO).

There are different types of Medicare health plans. Humana Gold Plus H0108-004 (HMO) is a Medicare Advantage HMO Plan (HMO stands for Health Maintenance Organization). Like all Medicare health plans, this Medicare HMO is approved by Medicare and run by a private company.

Section 1.2	What is the Evidence of Coverage booklet about?
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This Evidence of Coverage booklet tells you how to get your Medicare medical care and prescription drugs covered through our plan. This booklet explains your rights and responsibilities, what is covered, and what you pay as a member of the plan.

This plan, Humana Gold Plus H0108-004 (HMO), is offered by HUMANA HEALTH PLAN OF CALIFORNIA, INC. (When this Evidence of Coverage says "we," "us," or "our," it means HUMANA HEALTH PLAN OF CALIFORNIA, INC. When it says "plan" or "our plan," it means Humana Gold Plus H0108-004 (HMO).)

The word "coverage" and "covered services" refers to the medical care and services and the prescription drugs available to you as a member of Humana Gold Plus H0108-004 (HMO).

Section 1.3	What does this chapter tell you?
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Look through Chapter 1 of this Evidence of Coverage to learn:

- What makes you eligible to be a plan member?
- What is your plan's service area?
- What materials will you get from us?
- What is your plan premium and how can you pay it?
- How do you keep the information in your membership record up to date?

Section 1.4	What if you are new to Humana Gold Plus H0108-004 (HMO)?
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If you are a new member, then it's important for you to learn what the plan's rules are and what services are available to you. We encourage you to set aside some time to look through this Evidence of Coverage booklet.

If you are confused or concerned or just have a question, please contact Customer Care (phone numbers are printed on the back cover of this booklet).

Section 1.5 Legal information about the Evidence of Coverage

It's part of our contract with you

This Evidence of Coverage is part of our contract with you about how Humana Gold Plus H0108-004 (HMO) covers your care. Other parts of this contract include your enrollment form, the Prescription Drug Guide (Formulary), and any notices you receive from us about changes to your coverage or conditions that affect your coverage. These notices are sometimes called "riders" or "amendments."

The contract is in effect for months in which you are enrolled in Humana Gold Plus H0108-004 (HMO) between January 1, 2014 and December 31, 2014.

Each calendar year, Medicare allows us to make changes to the plans that we offer. This means we can change the costs and benefits of Humana Gold Plus H0108-004 (HMO) after December 31, 2014. We can also choose to stop offering the plan, or to offer it in a different service area, after December 31, 2014.

Medicare must approve our plan each year

Medicare (the Centers for Medicare & Medicaid Services) must approve Humana Gold Plus H0108-004 (HMO) each year. You can continue to get Medicare coverage as a member of our plan as long as we choose to continue to offer the plan and Medicare renews its approval of the plan.

SECTION 2 What makes you eligible to be a plan member?

Section 2.1 Your eligibility requirements

You are eligible for membership in our plan as long as:

- You live in our geographic service area (Section 2.3 below describes our service area)
- -- and -- you have both Medicare Part A and Medicare Part B
- -- and -- you do not have End-Stage Renal Disease (ESRD), with limited exceptions, such as if you develop ESRD when you are already a member of a plan that we offer, or you were a member of a different plan that was terminated.

Section 2.2 What are Medicare Part A and Medicare Part B?

When you first signed up for Medicare, you received information about what services are covered under Medicare Part A and Medicare Part B. Remember:

- Medicare Part A generally helps cover services furnished by institutional providers such as hospitals (for inpatient services), skilled nursing facilities, or home health agencies.
- Medicare Part B is for most other medical services (such as physician's services and other outpatient services) and certain items (such as durable medical equipment and supplies).

Section 2.3 Here is the plan service area for Humana Gold Plus H0108-004 (HMO)

Although Medicare is a federal program, Humana Gold Plus H0108-004 (HMO) is available only to individuals who live in our plan service area. To remain a member of our plan, you must keep living in this service area. The service area is described below.

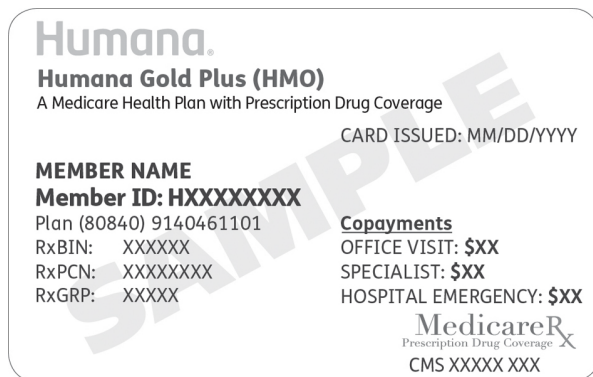
Our service area includes the following county/counties in California: Fresno, Kings, Madera Counties, CA.

If you plan to move out of the service area, please contact Customer Care (phone numbers are printed on the back cover of this booklet). When you move, you will have a Special Enrollment Period that will allow you to switch to Original Medicare or enroll in a Medicare health or drug plan that is available in your new location.

It is also important that you call Social Security if you move or change your mailing address. You can find phone numbers and contact information for Social Security in Chapter 2, Section 5.

SECTION 3 What other materials will you get from us?**Section 3.1 Your plan membership card - Use it to get all covered care and prescription drugs**

While you are a member of our plan, you must use your membership card for our plan whenever you get any services covered by this plan and for prescription drugs you get at network pharmacies. Here's a sample membership card to show you what yours will look like:



As long as you are a member of our plan **you must not use your red, white, and blue Medicare card** to get covered medical services (with the exception of routine clinical research studies and hospice services). Keep your red, white, and blue Medicare card in a safe place in case you need it later.

Here's why this is so important: If you get covered services using your red, white, and blue Medicare card instead of using your Humana Gold Plus H0108-004 (HMO) membership card while you are a plan member, you may have to pay the full cost yourself.

If your plan membership card is damaged, lost, or stolen, call Customer Care right away and we will send you a new card. (Phone numbers for Customer Care are printed on the back cover of this booklet.)

Section 3.2 The Provider Directory: Your guide to all providers and pharmacies in the plan's network

The Provider Directory lists our network providers.

What are "network providers"?

Network providers are the doctors and other health care professionals, medical groups, hospitals, and other health care facilities that have an agreement with us to accept our payment and any plan cost sharing as payment in full. We have arranged for these providers to deliver covered services to members in our plan.

Why do you need to know which providers are part of our network?

It is important to know which providers are part of our network because, with limited exceptions, while you are a member of our plan you must use network providers to get your medical care and services. The only exceptions are emergencies, urgently needed care when the network is not available (generally, when you are out of the area), out-of-area dialysis services, and cases in which Humana Gold Plus H0108-004 (HMO) authorizes use of out-of-network providers. See Chapter 3 (Using the plan's coverage for your medical services) for more specific information about emergency, out-of-network, and out-of-area coverage.

What are "network pharmacies"?

Our Provider Directory gives you a complete list of our network pharmacies– that means all of the pharmacies that have agreed to fill covered prescriptions for our plan members.

Why do you need to know about network pharmacies?

You can use the Provider Directory to find the network pharmacy you want to use. This is important because, with few exceptions, you must get your prescriptions filled at one of our network pharmacies if you want our plan to cover (help you pay for) them.

If you don't have the Provider Directory, you can get a copy from Customer Care (phone numbers are printed on the back cover of this booklet). You may ask Customer Care for more information about our network providers, including their qualifications. You can also see the Provider Directory at **Humana.com** or download it from this website. Both Customer Care and the website can give you the most up-to-date information about changes in our network pharmacies.

Section 3.3 The plan's Prescription Drug Guide (Formulary)

The plan has a Prescription Drug Guide (Formulary). We call it the "Drug Guide" for short. It tells which Part D prescription drugs are covered by Humana Gold Plus H0108-004 (HMO). The drugs on this list are selected by the plan with the help of a team of doctors and pharmacists. The list must meet requirements set by Medicare. Medicare has approved the Humana Gold Plus H0108-004 (HMO) Drug Guide.

The Drug Guide also tells you if there are any rules that restrict coverage for your drugs.

We will send you a copy of the Drug Guide. The Drug Guide we send to you includes information for the covered drugs that are most commonly used by our members. However, we cover additional drugs that are not included in the printed Drug Guide. If one of your drugs is not listed in the Drug Guide, you should visit our website or contact

Customer Care to find out if we cover it. To get the most complete and current information about which drugs are covered, you can visit the plan's website (**Humana.com**) or call Customer Care (phone numbers are printed on the back cover of this booklet).

Section 3.4 SmartSummary: Reports with a summary of payments made for your Part D prescription drugs

When you use your Part D prescription drug benefits, we will send you a summary report to help you understand and keep track of payments for your Part D prescription drugs. This summary report is called SmartSummary®.

SmartSummary tells you the total amount you have spent on your Part D prescription drugs and the total amount we have paid for each of your Part D prescription drugs during the month. Chapter 6 (What you pay for your Part D prescription drugs) gives more information about SmartSummary and how it can help you keep track of your drug coverage.

SmartSummary is also available upon request. To get a copy, please contact Customer Care (phone numbers are printed on the back cover of this booklet).

SECTION 4 Your monthly premium for Humana Gold Plus H0108-004 (HMO)

Section 4.1 How much is your plan premium?

You do not pay a separate monthly plan premium for Humana Gold Plus H0108-004 (HMO). You must continue to pay your Medicare Part B premium (unless your Part B premium is paid for you by Medicaid or another third party).

In some situations, your plan premium could be more

In some situations, your plan premium could be more than the amount listed above in Section 4.1. These situations are described below.

- If you signed up for extra benefits, also called "optional supplemental benefits", then you pay an additional premium each month for these extra benefits. If you have any questions about your plan premiums, please call Customer Care (phone numbers are printed on the back cover of this booklet).

MyOptionSM Dental – High PPO: **\$25.30** additional monthly premium

MyOptionSM Vision: **\$15.30** additional monthly premium

MyOptionSM Plus: **\$24.30** additional monthly premium

- Some members are required to pay a **late enrollment penalty** because they did not join a Medicare drug plan when they first became eligible or because they had a continuous period of 63 days or more when they didn't have "creditable" prescription drug coverage. ("Creditable" means the drug coverage is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage.) For these members, the late enrollment penalty is added to the plan's monthly premium. Their premium amount will be the monthly plan premium plus the amount of their late enrollment penalty.

- If you are required to pay the late enrollment penalty, the amount of your penalty depends on how long you waited before you enrolled in drug coverage or how many months you were without drug coverage after you became eligible. Chapter 6, Section 10 explains the late enrollment penalty.

If you have a late enrollment penalty and do not pay it, you could be disenrolled from the plan.

Many members are required to pay other Medicare premiums

Many members are required to pay other Medicare premiums. As explained in Section 2 above, in order to be eligible for our plan, you must be entitled to Medicare Part A and enrolled in Medicare Part B. For that reason, some plan members (those who aren't eligible for premium-free Part A) pay a premium for Medicare Part A. And most plan members pay a premium for Medicare Part B. **You must continue paying your Medicare premiums to remain a member of the plan.**

Some people pay an extra amount for Part D because of their yearly income. If your income is **\$85,000** or above for an individual (or married individuals filing separately) or **\$170,000** or above for married couples, you must pay an extra amount directly to the government (not the Medicare plan) for your Medicare Part D coverage.

- If you are required to pay the extra amount and you do not pay it, you will be disenrolled from the plan and lose prescription drug coverage.
- If you have to pay an extra amount, Social Security, not your Medicare plan, will send you a letter telling you what that extra amount will be.
- For more information about Part D premiums based on income, go to Chapter 6, Section 11 of this booklet. You can also visit <http://www.medicare.gov> on the web or call 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048. Or you may call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778.

Your copy of Medicare & You 2014 gives information about the Medicare premiums in the section called "2014 Medicare Costs." This explains how the Medicare Part B and Part D premiums differ for people with different incomes. Everyone with Medicare receives a copy of Medicare & You each year in the fall. Those new to Medicare receive it within a month after first signing up. You can also download a copy of Medicare & You 2014 from the Medicare website (<http://www.medicare.gov>). Or, you can order a printed copy by phone at 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users call 1-877-486-2048.

Section 4.2 If you pay a Part D late enrollment penalty, there are several ways you can pay your penalty

If you pay a Part D late enrollment penalty, there are four ways you can pay the penalty. Members select a payment option choice at the time of enrollment. If you wish to change your payment option, you can easily do so by contacting Customer Care, or you can visit our eBilling site at **Humana.com** to set up a payment option for your account.

1. Login to **Humana.com** with your user id and password. If you don't have a user name or password, click on "Register for MyHumana."
2. Click on the eBilling link under "My Claims & Spending" tab.
3. Once you click on the eBilling link, you'll be able to make a payment. You can also check your account balance and review an invoice summary.

If you decide to change the way you pay your late enrollment penalty, it can take up to three months for your new payment method to take effect. While we are processing your request for a new payment method, you are responsible for making sure that your late enrollment penalty is paid on time.

Option 1: You can pay by check

Checks should be made out to the plan and sent to the plan. Checks should not be made out to the Centers for Medicare & Medicaid Services or the U.S. Department of Health and Human Services (HHS) and should not be sent to these agencies.

You may decide to pay your late enrollment penalty directly to our plan with a check or money order using the coupon book Humana will provide to you. Your late enrollment penalty payment will always be due on the first day of the month.

Option 2: Automatically withdrawn from your checking or savings account, or charged directly to your credit card or debit card

Instead of paying by check, you can have your late enrollment penalty automatically withdrawn from your checking or savings account, or charged directly to your credit card or debit card. Your late enrollment penalty will be automatically withdrawn from your checking or savings account on the third working day of each month or charged directly to your credit card or debit card monthly. Please call our Customer Care department to set up your automatic withdrawal or credit or debit card payments.

Options 3 and 4: You can have the late enrollment penalty taken out of your monthly Social Security check or Railroad Retiree Board (RRB) benefit

You can have the late enrollment penalty taken out of your monthly Social Security or Railroad Retiree Board benefit check. You can contact Customer Care for more information on how to pay your late enrollment penalty this way or you can visit our eBilling site at Humana.com to set up your SSA or RRB payment option. We will be happy to help you set this up. (Phone numbers for Customer Care are printed on the back cover of this booklet.)

What to do if you are having trouble paying your late enrollment penalty

Your late enrollment penalty is due in our office by the first day of the month. If we have not received your penalty payment by the 15th of the month, we will send you a notice telling you that your plan membership will end if we do not receive your late enrollment penalty within six months.

If you are having trouble paying your late enrollment penalty on time, please contact Customer Care to see if we can direct you to programs that will help with your penalty. (Phone numbers for Customer Care are printed on the back cover of this booklet.)

If we end your membership with the plan because you did not pay your late enrollment penalty, then you may not be able to receive Part D coverage until the following year if you enroll in a new plan during the annual enrollment period. During the annual enrollment period, you may either join a stand-alone prescription drug plan or a health plan that also provides drug coverage. (If you go without "creditable" drug coverage for more than 63 days, you may have to pay a late enrollment penalty for as long as you have Part D coverage.)

If we end your membership because you did not pay your late enrollment penalty, you will have health coverage under Original Medicare.

At the time we end your membership, you may still owe us for the penalty you have not paid. We have the right to pursue collection of the penalty amount you owe. In the future, if you want to enroll again in our plan (or another plan that we offer), you will need to pay the amount you owe before you can enroll.

If you think we have wrongfully ended your membership, you have a right to ask us to reconsider this decision by making a complaint. Chapter 9, Section 10 of this booklet tells how to make a complaint. If you had an emergency circumstance that was out of your control and it caused you to not be able to pay your premiums within our grace period, you can ask Medicare to reconsider this decision by calling 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.

Section 4.3 Can we change your monthly plan premium during the year?

No. We are not allowed to begin charging a monthly plan premium during the year. If the monthly plan premium changes for next year we will tell you in September and the change will take effect on January 1.

However, in some cases, you may need to start paying or may be able to stop paying a late enrollment penalty. (The late enrollment penalty may apply if you had a continuous period of 63 days or more when you didn't have "creditable" prescription drug coverage.) This could happen if you become eligible for the "Extra Help" program or if you lose your eligibility for the "Extra Help" program during the year:

- If you currently pay the late enrollment penalty and become eligible for "Extra Help" during the year, you would be able to stop paying your penalty.
- If the "Extra Help" program is currently paying your late enrollment penalty and you lose your eligibility during the year, you would need to start paying your penalty.

You can find out more about the "Extra Help" program in Chapter 2, Section 7.

SECTION 5 Please keep your plan membership record up to date

Section 5.1 How to help make sure that we have accurate information about you

Your membership record has information from your enrollment form, including your address and telephone number. It shows your specific plan coverage including your Primary Care Physician.

The doctors, hospitals, pharmacists, and other providers in the plan's network need to have correct information about you. **These network providers use your membership record to know what services and drugs are covered and the cost-sharing amounts for you.** Because of this, it is very important that you help us keep your information up to date.

Let us know about these changes:

- Changes to your name, your address, or your phone number
- Changes in any other health insurance coverage you have (such as from your employer, your spouse's employer, workers' compensation, or Medicaid)
- If you have any liability claims, such as claims from an automobile accident
- If you have been admitted to a nursing home
- If you receive care in an out-of-area or out-of-network hospital or emergency room
- If your designated responsible party (such as a caregiver) changes

- If you are participating in a clinical research study

If any of this information changes, please let us know by calling Customer Care (phone numbers are printed on the back cover of this booklet).

It is also important to contact Social Security if you move or change your mailing address. You can find phone numbers and contact information for Social Security in Chapter 2, Section 5.

Read over the information we send you about any other insurance coverage you have

Medicare requires that we collect information from you about any other medical or drug insurance coverage that you have. That's because we must coordinate any other coverage you have with your benefits under our plan. (For more information about how our coverage works when you have other insurance, see Section 7 in this chapter.)

Once each year, we will send you a letter that lists any other medical or drug insurance coverage that we know about. Please read over this information carefully. If it is correct, you don't need to do anything. If the information is incorrect, or if you have other coverage that is not listed, please call Customer Care (phone numbers are printed on the back cover of this booklet).

SECTION 6 We protect the privacy of your personal health information

Section 6.1 We make sure that your health information is protected

Federal and state laws protect the privacy of your medical records and personal health information. We protect your personal health information as required by these laws.

For more information about how we protect your personal health information, please go to Chapter 8, Section 1.4 of this booklet.

SECTION 7 How other insurance works with our plan

Section 7.1 Which plan pays first when you have other insurance?

When you have other insurance (like employer group health coverage), there are rules set by Medicare that decide whether our plan or your other insurance pays first. The insurance that pays first is called the "primary payer" and pays up to the limits of its coverage. The one that pays second, called the "secondary payer," only pays if there are costs left uncovered by the primary coverage. The secondary payer may not pay all of the uncovered costs.

These rules apply for employer or union group health plan coverage:

- If you have retiree coverage, Medicare pays first.
- If your group health plan coverage is based on your or a family member's current employment, who pays first depends on your age, the size of the employer, and whether you have Medicare based on age, disability, or End-stage Renal Disease (ESRD):
 - If you're under 65 and disabled and you or your family member is still working, your plan pays first if the employer has 100 or more employees or at least one employer in a multiple employer plan has more than 100 employees.

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- If you're over 65 and you or your spouse is still working, the plan pays first if the employer has 20 or more employees or at least one employer in a multiple employer plan has more than 20 employees.
- If you have Medicare because of ESRD, your group health plan will pay first for the first 30 months after you become eligible for Medicare.

These types of coverage usually pay first for services related to each type:

- No-fault insurance (including automobile insurance)
- Liability (including automobile insurance)
- Black lung benefits
- Workers' compensation

Medicaid and TRICARE never pay first for Medicare-covered services. They only pay after Medicare, employer group health plans, and/or Medigap have paid.

If you have other insurance, tell your doctor, hospital, and pharmacy. If you have questions about who pays first, or you need to update your other insurance information, call Customer Care (phone numbers are printed on the back cover of this booklet.) You may need to give your plan member ID number to your other insurers (once you have confirmed their identity) so your bills are paid correctly and on time.

CHAPTER 2. Important phone numbers and resources

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SECTION 1 Humana Gold Plus H0108-004 (HMO) contacts

(how to contact us, including how to reach Customer Care at the plan)

How to contact our plan's Customer Care

For assistance with claims, billing, or member card questions, please call or write to Humana Gold Plus H0108-004 (HMO) Customer Care. We will be happy to help you.

Customer Care	
CALL	1-800-457-4708 Calls to this number are free. (A Customer Care representative will be available to answer your call directly during the annual enrollment period and 60 days after from 8 a.m. until 8 p.m.) However, beginning February 15, 2014, your call may be handled by our automated phone system on Saturdays, Sundays, and some Public Holidays. When leaving a message, simply select the reason for your call from the automated list and a knowledgeable representative will return your call by the end of the next working day. Customer Care also has free language interpreter services available for non-English speakers.
TTY	711 Hours of operation are the same as above. This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking. Calls to this number are free.
FAX	1-877-837-7741
WRITE	Humana, P.O. Box 14168, Lexington, KY 40512-4168
WEBSITE	Humana.com

How to contact us when you are asking for a coverage decision about your medical care

A coverage decision is a decision we make about your benefits and coverage or about the amount we will pay for your medical services. For more information on asking for coverage decisions about your medical care, see Chapter 9 (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)).

You may call us if you have questions about our coverage decision process.

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Chapter 2: Important phone numbers and resources

Coverage Decisions for Medical Care	
CALL	<p>1-800-457-4708, For fast (expedited) coverage decisions, call 1-866-737-5113</p> <p>8 a.m. to 8 p.m. seven days a week from Oct. 1 – Feb. 14. 8 a.m. to 8 p.m. Monday-Friday from Feb. 15 - Sept. 30. You can leave us a voicemail message after hours, Saturdays, Sundays and some public holidays. Just leave a message and select the reason for your call from the automated list. We'll call back by the end of the next business day. Please have your Humana ID card with you when you call.</p> <p>Calls to this number are free.</p>
TTY	<p>711</p> <p>Hours of operation are the same as above.</p> <p>This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking.</p> <p>Calls to this number are free.</p>
FAX	1-888-200-7440 for expedited coverage decisions only
WRITE	Humana, P.O. Box 14168, Lexington, KY 40512-4168

How to contact us when you are making an appeal about your medical care

An appeal is a formal way of asking us to review and change a coverage decision we have made. For more information on making an appeal about your medical care, see Chapter 9 (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)).

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 2: Important phone numbers and resources

Appeals for Medical Care	
CALL	<p>1-800-457-4708</p> <p>8 a.m. to 8 p.m. seven days a week from Oct. 1 – Feb. 14. 8 a.m. to 8 p.m. Monday-Friday from Feb. 15 - Sept. 30. You can leave us a voicemail message after hours, Saturdays, Sundays and some public holidays. Just leave a message and select the reason for your call from the automated list. We'll call back by the end of the next business day. Please have your Humana ID card with you when you call.</p> <p>Calls to this number are free.</p>
TTY	<p>711</p> <p>Hours of operation are the same as above.</p> <p>This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking.</p> <p>Calls to this number are free.</p>
FAX	1-800-949-2961 for expedited appeals only.
WRITE	Humana Grievances and Appeals Dept., P.O. Box 14165, Lexington, KY 40512-4165

How to contact us when you are making a complaint about your medical care

You can make a complaint about us or one of our network providers, including a complaint about the quality of your care. This type of complaint does not involve coverage or payment disputes. (If your problem is about the plan's coverage or payment, you should look at the section above about making an appeal.) For more information on making a complaint about your medical care, see Chapter 9 (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)).

Complaints about Medical Care

CALL	1-800-457-4708 8 a.m. to 8 p.m. seven days a week from Oct. 1 – Feb. 14. 8 a.m. to 8 p.m. Monday-Friday from Feb. 15 – Sept. 30. You can leave us a voicemail message after hours, Saturdays, Sundays and some public holidays. Just leave a message and select the reason for your call from the automated list. We'll call back by the end of the next business day. Please have your Humana ID card with you when you call. Calls to this number are free.
TTY	711 Hours of operation are the same as above. This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking. Calls to this number are free.
FAX	1-800-949-2961, for expedited grievances only.
WRITE	Humana Grievances and Appeals Dept., P.O. Box 14165, Lexington, KY 40512-4165
MEDICARE WEBSITE	You can submit a complaint about Humana Gold Plus H0108-004 (HMO) directly to Medicare. To submit an online complaint to Medicare, go to www.medicare.gov/MedicareComplaintForm/home.aspx .

How to contact us when you are asking for a coverage decision about your Part D prescription drugs

A coverage decision is a decision we make about your benefits and coverage or about the amount we will pay for your Part D prescription drugs. For more information on asking for coverage decisions about your Part D prescription drugs, see Chapter 9 (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)).

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)

Chapter 2: Important phone numbers and resources

Coverage Decisions for Part D Prescription Drugs

CALL	1-800-555-2546, 24 hours a day, seven days a week. Calls to this number are free.
TTY	711 Hours of operation are the same as above. This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking. Calls to this number are free.
FAX	1-877-486-2621 for coverage determinations only.
WRITE	Humana Clinical Pharmacy Review, Attn: Medicare Part D Coverage Determinations, P.O. Box 33008, Louisville, KY 40232
WEBSITE	Humana.com

How to contact us when you are making an appeal about your Part D prescription drugs

An appeal is a formal way of asking us to review and change a coverage decision we have made. For more information on making an appeal about your Part D prescription drugs, see Chapter 9 (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)).

Appeals for Part D Prescription Drugs

CALL	1-800-457-4708 8 a.m. to 8 p.m. seven days a week from Oct. 1 – Feb. 14. 8 a.m. to 8 p.m. Monday-Friday from Feb. 15 – Sept. 30. You can leave us a voicemail message after hours, Saturdays, Sundays and some public holidays. Just leave a message and select the reason for your call from the automated list. We'll call back by the end of the next business day. Please have your Humana ID card with you when you call. Calls to this number are free.
TTY	711 Hours of operation are the same as above. This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking. Calls to this number are free.
FAX	1-800-949-2961 for expedited appeals only.
WRITE	Humana Grievances and Appeals Dept., P.O. Box 14165, Lexington, KY 40512-4165
WEBSITE	Humana.com

How to contact us when you are making a complaint about your Part D prescription drugs

You can make a complaint about us or one of our network pharmacies, including a complaint about the quality of your care. This type of complaint does not involve coverage or payment disputes. (If your problem is about the plan's coverage or payment, you should look at the section above about making an appeal.) For more information on making a complaint about your Part D prescription drugs, see Chapter 9 (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)).

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 2: Important phone numbers and resources

Complaints about Part D Prescription Drugs

CALL	<p>1-800-457-4708</p> <p>8 a.m. to 8 p.m. seven days a week from Oct. 1 – Feb. 14. 8 a.m. to 8 p.m. Monday-Friday from Feb. 15 - Sept. 30. You can leave us a voicemail message after hours, Saturdays, Sundays and some public holidays. Just leave a message and select the reason for your call from the automated list. We'll call back by the end of the next business day. Please have your Humana ID card with you when you call.</p> <p>Calls to this number are free.</p>
TTY	<p>711</p> <p>Hours of operation are the same as above.</p> <p>This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking.</p> <p>Calls to this number are free.</p>
FAX	1-800-949-2961, for expedited grievances only.
WRITE	Humana Grievances and Appeals Dept., P.O. Box 14165, Lexington, KY 40512-4165
MEDICARE WEBSITE	You can submit a complaint about Humana Gold Plus H0108-004 (HMO) directly to Medicare. To submit an online complaint to Medicare, go to www.medicare.gov/MedicareComplaintForm/home.aspx .

Where to send a request asking us to pay for our share of the cost for medical care or a drug you have received

For more information on situations in which you may need to ask us for reimbursement or to pay a bill you have received from a provider, see Chapter 7 (Asking us to pay our share of a bill you have received for covered medical services or drugs).

Please note: If you send us a payment request and we deny any part of your request, you can appeal our decision. See Chapter 9 (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)) for more information.

Payment Requests	
CALL	1-800-457-4708 8 a.m. to 8 p.m. seven days a week from Oct. 1 – Feb. 14. 8 a.m. to 8 p.m. Monday-Friday from Feb. 15 - Sept. 30. You can leave us a voicemail message after hours, Saturdays, Sundays and some public holidays. Just leave a message and select the reason for your call from the automated list. We'll call back by the end of the next business day. Please have your Humana ID card with you when you call. Calls to this number are free.
TTY	711 Hours of operation are the same as above. This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking. Calls to this number are free.
WRITE	Humana, P.O. Box 14168, Lexington, KY 40512-4168
WEBSITE	Humana.com

SECTION 2 **Medicare**

(how to get help and information directly from the federal Medicare program)

Medicare is the federal health insurance program for people 65 years of age or older, some people under age 65 with disabilities, and people with End-Stage Renal Disease (permanent kidney failure requiring dialysis or a kidney transplant).

The federal agency in charge of Medicare is the Centers for Medicare & Medicaid Services (sometimes called “CMS”). This agency contracts with Medicare Advantage organizations, including us.

Medicare	
CALL	<p>1-800-MEDICARE, or 1-800-633-4227</p> <p>Calls to this number are free.</p> <p>24 hours a day, 7 days a week.</p>
TTY	<p>1-877-486-2048</p> <p>This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking.</p> <p>Calls to this number are free.</p>
WEBSITE	<p>http://www.medicare.gov</p> <p>This is the official government website for Medicare. It gives you up-to-date information about Medicare and current Medicare issues. It also has information about hospitals, nursing homes, physicians, home health agencies, and dialysis facilities. It includes booklets you can print directly from your computer. You can also find Medicare contacts in your state.</p> <p>The Medicare website also has detailed information about your Medicare eligibility and enrollment options with the following tools:</p> <ul style="list-style-type: none">• Medicare Eligibility Tool: Provides Medicare eligibility status information.• Medicare Plan Finder: Provides personalized information about available Medicare prescription drug plans, Medicare health plans, and Medigap (Medicare Supplement Insurance) policies in your area. These tools provide an <u>estimate</u> of what your out-of-pocket costs might be in different Medicare plans. <p>You can also use the website to tell Medicare about any complaints you have about Humana Gold Plus H0108-004 (HMO):</p> <ul style="list-style-type: none">• Tell Medicare about your complaint: You can submit a complaint about Humana Gold Plus H0108-004 (HMO) directly to Medicare. To submit a complaint to Medicare, go to www.medicare.gov/MedicareComplaintForm/home.aspx. Medicare takes your complaints seriously and will use this information to help improve the quality of the Medicare program. <p>If you don't have a computer, your local library or senior center may be able to help you visit this website using its computer. Or, you can call Medicare and tell them what information you are looking for. They will find the information on the website, print it out, and send it to you. (You can call Medicare at 1-800-MEDICARE (1-800-633- 4227), 24 hours a day, 7 days a week. TTY users should call 1-877- 486-2048.)</p>

SECTION 3 State Health Insurance Assistance Program

(free help, information, and answers to your questions about Medicare)

The State Health Insurance Assistance Program (SHIP) is a government program with trained counselors in every state.

The State Health Insurance Assistance Program (SHIP) is independent (not connected with any insurance company or health plan). It is a state program that gets money from the federal government to give free local health insurance counseling to people with Medicare.

State Health Insurance Assistance Program (SHIP) counselors can help you with your Medicare questions or problems. They can help you understand your Medicare rights, help you make complaints about your medical care or treatment, and help you straighten out problems with your Medicare bills. State Health Insurance Assistance Program (SHIP) counselors can also help you understand your Medicare plan choices and answer questions about switching plans.

Contact information for your State Health Insurance Assistance Program (SHIP) can be found in “Exhibit A” in the back of this document.

SECTION 4 Quality Improvement Organization

(paid by Medicare to check on the quality of care for people with Medicare)

There is a Quality Improvement Organization (QIO) for each state.

The Quality Improvement Organization (QIO) has a group of doctors and other health care professionals who are paid by the federal government. This organization is paid by Medicare to check on and help improve the quality of care for people with Medicare. The Quality Improvement Organization (QIO) is an independent organization. It is not connected with our plan.

You should contact your Quality Improvement Organization (QIO) in any of these situations:

- You have a complaint about the quality of care you have received.
- You think coverage for your hospital stay is ending too soon.
- You think coverage for your home health care, skilled nursing facility care, or Comprehensive Outpatient Rehabilitation Facility (CORF) services are ending too soon.

Contact information for your state Quality Improvement Organization (QIO) can be found in “Exhibit A” in the back of this document.

SECTION 5 Social Security

Social Security is responsible for determining eligibility and handling enrollment for Medicare. U.S. citizens who are 65 or older, or who have a disability or End-Stage Renal Disease and meet certain conditions, are eligible for Medicare. If you are already getting Social Security checks, enrollment into Medicare is automatic. If you are not getting Social Security checks, you have to enroll in Medicare. Social Security handles the enrollment process for Medicare. To apply for Medicare, you can call Social Security or visit your local Social Security office.

Social Security is also responsible for determining who has to pay an extra amount for their Part D drug coverage because they have a higher income. If you got a letter from Social Security telling you that you have to pay the extra amount and have questions about the amount or if your income went down because of a life-changing event, you can call Social Security to ask for a reconsideration.

If you move or change your mailing address, it is important that you contact Social Security to let them know.

Social Security	
CALL	<p>1-800-772-1213</p> <p>Calls to this number are free.</p> <p>Available 7 a.m. to 7 p.m., Monday through Friday.</p> <p>You can use Social Security's automated telephone services to get recorded information and conduct some business 24 hours a day.</p>
TTY	<p>1-800-325-0778</p> <p>This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking.</p> <p>Calls to this number are free.</p> <p>Available 7 a.m. to 7 p.m., Monday through Friday.</p>
WEBSITE	http://www.ssa.gov

SECTION 6

Medicaid

(a joint federal and state program that helps with medical costs for some people with limited income and resources)

Medicaid is a joint federal and state government program that helps with medical costs for certain people with limited incomes and resources. Some people with Medicare are also eligible for Medicaid.

In addition, there are programs offered through Medicaid that help people with Medicare pay their Medicare costs, such as their Medicare premiums. These "Medicare Savings Programs" help people with limited income and resources save money each year:

- **Qualified Medicare Beneficiary (QMB):** Helps pay Medicare Part A and Part B premiums, and other cost sharing (like deductibles, coinsurance, and copayments). (Some people with QMB are also eligible for full Medicaid benefits (QMB+).)
- **Specified Low-Income Medicare Beneficiary (SLMB):** Helps pay Part B premiums. (Some people with SLMB are also eligible for full Medicaid benefits (SLMB+).)
- **Qualified Individual (QI):** Helps pay Part B premiums.
- **Qualified Disabled & Working Individuals (QDWI):** Helps pay Part A premiums.

To find out more about Medicaid and its programs, contact your state Medicaid office. Contact information for your state Medicaid Office can be found in "Exhibit A" in the back of this document.

SECTION 7 Information about programs to help people pay for their prescription drugs

Medicare's "Extra Help" Program

Medicare provides "Extra Help" to pay prescription drug costs for people who have limited income and resources. Resources include your savings and stocks, but not your home or car. If you qualify, you get help paying for any Medicare drug plan's monthly premium, and prescription copayments or coinsurance. This "Extra Help" also counts toward your out-of-pocket costs.

People with limited income and resources may qualify for "Extra Help". Some people automatically qualify for "Extra Help" and don't need to apply. Medicare mails a letter to people who automatically qualify for "Extra Help".

You may be able to get "Extra Help" to pay for your prescription drug premiums and costs. To see if you qualify for getting "Extra Help", call:

- 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048, 24 hours a day, 7 days a week;
- The Social Security Office at 1-800-772-1213, between 7 am to 7 pm, Monday through Friday. TTY users should call 1-800-325-0778; or
- Your State Medicaid Office. (See "Exhibit A" for contact information.)

If you believe you have qualified for "Extra Help" and you believe that you are paying an incorrect cost-sharing amount when you get your prescription at a pharmacy, our plan has established a process that allows you to either request assistance in obtaining evidence of your proper copayment level, or, if you already have the evidence, to provide this evidence to us.

- At the pharmacy you can show proof of Extra Help by providing any of the following:
 - A copy of your Medicaid card with your name and eligibility date during a month after June of the previous calendar year;
 - One of the following letters from the Social Security Administration (SSA), showing Extra Help status (Important Information, Award Letter, Notice of Change or Notice of Action);
 - A copy of a state document that confirms active Medicaid status during a month after June of the previous calendar year;
 - A screen print from the state Medicaid system showing your Medicaid status during a month after June of the previous calendar year;
 - A print out from the state electronic enrollment file showing Medicaid status during a month after June of the previous calendar year;
 - Any other documentation provided by the state showing Medicaid status during a month after June of the previous calendar year;
 - A letter from SSA showing that the individual receives SSI;
 - A remittance from the facility showing Medicaid payment for a full calendar month for that individual during a month after June of the previous calendar year;
 - A copy of a state document that confirms Medicaid payment on behalf of the individual to the facility for a full calendar month after June of the previous calendar year;
 - A screen print from the State Medicaid systems showing that the individual's institutional status based on at least a full calendar month stay for Medicaid payment purposes during a month after June of the previous calendar year.

Please note that this Extra Help proof must be confirmed by a Pharmacist, CMS representative, State Medicaid official, or a Humana Sales Agent. The Extra Help proof must also reflect the date for the time period in question.

Once we have updated your information at the pharmacy, you can mail proof to the following address to maintain this copayment level: Humana, P.O. Box 14168, Lexington, KY 40512-4168.

We will also follow-up with you by letter requesting that the proof be mailed back within 30 days of the date of the letter.

If you have any questions, please feel free to call Customer Care (phone numbers are on the back cover of this booklet).

- When we receive the evidence showing your copayment or coinsurance level, we will update our system so that you can pay the correct copayment or coinsurance when you get your next prescription at the pharmacy. If you overpay your copayment or coinsurance, we will reimburse you. Either we will forward a check to you in the amount of your overpayment or we will offset future copayments or coinsurance. If the pharmacy hasn't collected a copayment or coinsurance from you and is carrying your copayment or coinsurance as a debt owed by you, we may make the payment directly to the pharmacy. If a state paid on your behalf, we may make payment directly to the state. Please contact Customer Care if you have questions (phone numbers are printed on the back cover of this booklet).

Medicare Coverage Gap Discount Program

The Medicare Coverage Gap Discount Program is available nationwide. Because Humana Gold Plus H0108-004 (HMO) offers additional gap coverage during the Coverage Gap Stage, your out-of-pocket costs will sometimes be lower than the costs described here. Please go to Chapter 6, Section 6 for more information about your coverage during the Coverage Gap Stage.

The Medicare Coverage Gap Discount Program provides manufacturer discounts on brand name drugs to Part D enrollees who have reached the coverage gap and are not already receiving "Extra Help." A **50 percent** discount on the negotiated price (excluding the dispensing fee and vaccine administration fee, if any) is available for those brand name drugs from manufacturers that have agreed to pay the discount. The plan pays an additional **2.5 percent** and you pay the remaining **47.5 percent** for your brand drugs.

If you reach the coverage gap, we will automatically apply the discount when your pharmacy bills you for your prescription and your SmartSummary will show any discount provided. Both the amount you pay and the amount discounted by the manufacturer count toward your out-of-pocket costs as if you had paid them and moves you through the coverage gap.

You also receive some coverage for generic drugs. If you reach the coverage gap, the plan pays **28 percent** of the price for generic drugs and you pay the remaining **72 percent** of the price. The coverage for generic drugs works differently than the coverage for brand name drugs. For generic drugs, the amount paid by the plan (**28 percent**) does not count toward your out-of-pocket costs. Only the amount you pay counts and moves you through the coverage gap. Also, the dispensing fee is included as part of the cost of the drug.

If you have any questions about the availability of discounts for the drugs you are taking or about the Medicare Coverage Gap Discount Program in general, please contact Customer Care (phone numbers are printed on the back cover of this booklet).

SECTION 8 How to contact the Railroad Retirement Board

The Railroad Retirement Board is an independent federal agency that administers comprehensive benefit programs for the nation's railroad workers and their families. If you have questions regarding your benefits from the Railroad Retirement Board, contact the agency.

If you receive your Medicare through the Railroad Retirement Board, it is important that you let them know if you move or change your mailing address.

Railroad Retirement Board	
CALL	1-877-772-5772 Calls to this number are free. Available 9:00 a.m. to 3:30 p.m., Monday through Friday If you have a touch-tone telephone, recorded information and automated services are available 24 hours a day, including weekends and holidays.
TTY	1-312-751-4701 This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking. Calls to this number are <u>not</u> free.
WEBSITE	http://www.rrb.gov

SECTION 9 Do you have “group insurance” or other health insurance from an employer?

If you (or your spouse) get benefits from your (or your spouse's) employer or retiree group, call the employer/union benefits administrator or Customer Care if you have any questions. You can ask about your (or your spouse's) employer or retiree health benefits, premiums, or the enrollment period. (Phone numbers for Customer Care are printed on the back cover of this booklet.)

If you have other prescription drug coverage through your (or your spouse's) employer or retiree group, please contact **that group's benefits administrator**. The benefits administrator can help you determine how your current prescription drug coverage will work with our plan.

Chapter 3. Using the plan's coverage for your medical services

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SECTION 1 Things to know about getting your medical care covered as a member of our plan

This chapter explains what you need to know about using the plan to get your medical care covered. It gives definitions of terms and explains the rules you will need to follow to get the medical treatments, services, and other medical care that are covered by the plan.

For the details on what medical care is covered by our plan and how much you pay when you get this care, use the benefits chart in the next chapter, Chapter 4 (Medical Benefits Chart, what is covered and what you pay).

Section 1.1 What are "network providers" and "covered services"?

Here are some definitions that can help you understand how you get the care and services that are covered for you as a member of our plan:

- **"Providers"** are doctors and other health care professionals licensed by the state to provide medical services and care. The term "providers" also includes hospitals and other health care facilities.
- **"Network providers"** are the doctors and other health care professionals, medical groups, hospitals, and other health care facilities that have an agreement with us to accept our payment and your cost-sharing amount as payment in full. We have arranged for these providers to deliver covered services to members in our plan. The providers in our network generally bill us directly for care they give you. When you see a network provider, you usually pay only your share of the cost for their services.
- **"Covered services"** include all the medical care, health care services, supplies, and equipment that are covered by our plan. Your covered services for medical care are listed in the benefits chart in Chapter 4.

Section 1.2 Basic rules for getting your medical care covered by the plan

As a Medicare health plan, Humana Gold Plus H0108-004 (HMO) must cover all services covered by Original Medicare and must follow Original Medicare's coverage rules.

Humana Gold Plus H0108-004 (HMO) will generally cover your medical care as long as:

- **The care you receive is included in the plan's Medical Benefits Chart** (this chart is in Chapter 4 of this booklet).
- **The care you receive is considered medically necessary.** "Medically necessary" means that the services, supplies, or drugs are needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.
- **You have a network primary care physician (a PCP) who is providing and overseeing your care.** As a member of our plan, you must choose a network PCP (for more information about this, see Section 2.1 in this chapter).
 - In most situations, your network PCP must give you approval in advance before you can use other providers in the plan's network, such as specialists, hospitals, skilled nursing facilities, or home health care agencies. This is called giving you a "referral." For more information about this, see Section 2.3 of this chapter.
 - Referrals from your PCP are not required for emergency care or urgently needed care. There are also some other kinds of care you can get without having approval in advance from your PCP (for more information about this, see Section 2.2 of this chapter).

- **You must receive your care from a network provider** (for more information about this, see Section 2 in this chapter). In most cases, care you receive from an out-of-network provider (a provider who is not part of our plan's network) will not be covered. Here are three exceptions:
 - The plan covers emergency care or urgently needed care that you get from an out-of-network provider. For more information about this, and to see what emergency or urgently needed care means, see Section 3 in this chapter.
 - If you need medical care that Medicare requires our plan to cover and the providers in our network cannot provide this care, you can get this care from an out-of-network provider. You must obtain authorization from the plan prior to seeking care from an out-of-network provider. In this situation, you will pay the same as you would pay if you got the care from a network provider. For information about getting approval to see an out-of-network doctor, see Section 2.4 in this chapter.
 - Kidney dialysis services that you get at a Medicare-certified dialysis facility when you are temporarily outside the plan's service area.

SECTION 2 Use providers in the plan's network to get your medical care

Section 2.1 You must choose a Primary Care Physician (PCP) to provide and oversee your medical care

What is a "PCP" and what does the PCP do for you?

When you become a member of our plan, you must choose a plan physician to be your PCP. Your PCP is a physician who meets state requirements and is trained to give you basic medical care. Your Provider Directory will indicate which physicians may act as your PCP. As we explain below, you can get your routine or basic care from your PCP. Your PCP can also coordinate the rest of the covered services you get as a plan member. For example, in order to see a network specialist, you usually need to get your PCP's approval first (this is called getting a "referral" to a specialist).

This includes:

- Your x-rays
- Laboratory tests
- Therapies
- Care from doctors who are specialists
- Hospital admissions
- Follow-up care

"Coordinating" your services includes checking or consulting with other plan providers about your care and how it is going. If you need certain types of covered services or supplies, you must get approval in advance from your PCP (such as giving you a referral). In some cases, your PCP will need to get prior authorization (prior approval). Chapter 4 has more information on which services require prior authorization.

Since your PCP can provide and coordinate your medical care, you should have all of your past medical records sent to your PCP's office. Chapter 8 tells you how we will protect the privacy of your medical records and personal health information.

How do you get care from your PCP?

You will usually see your PCP first for most of your routine health care needs.

There are only a few types of covered services you may get on your own, without contacting your PCP first. For more information about which services do not require referrals, see Section 2.2 below.

If it is after normal business hours and you have a need for routine care, please call your PCP back during normal business hours. If you have an emergency or have an urgent need for care after normal business hours, see sections 3.1 Emergency Care or 3.2 Urgently Needed Care in this document. You may also call HumanaFirst, our 24 hour nurse advice line, at 1-800-622-9529 (TTY 711).

How do you choose your PCP?

You will receive a plan Provider Directory at the time of enrollment to help you select the PCP of your choice. The PCP you choose will be listed on your enrollment form. If you enroll at **Humana.com**, you will be directed to the plan's online Provider Directory to select the PCP of your choice. You can change your PCP at any time (as explained later in this section). If there is a particular plan specialist or hospital that you want to use, check first to be sure your PCP gives referrals to that specialist or uses that hospital. The name and office telephone number of your PCP is printed on your member ID card.

Changing your PCP

You may change your PCP for any reason, at any time. Also, it's possible that your PCP might leave our plan's network of providers and you would have to find a new PCP. Change requests received by the last working day of the month will usually be effective on the first day of the following month. To change your PCP, call Customer Care.


When you call, be sure to tell Customer Care if you are seeing specialists or getting other covered services that needed your PCP's approval (such as home health services and durable medical equipment). Customer Care will help make sure that you can continue with the specialty care and other services you have been getting when you change your PCP. They will also check to be sure the PCP you want to switch to is accepting new patients. Customer Care will change your membership record to show the name of your new PCP, and tell you when the change to your new PCP will take effect.

They will also send you a new membership card that shows the name and phone number of your new PCP.

Section 2.2	What kinds of medical care can you get without getting approval in advance from your PCP?
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You can get services such as those listed below without getting approval in advance from your PCP.

- Routine women's health care, which includes breast exams, screening mammograms (x-rays of the breast), Pap tests, and pelvic exams from network providers.
- Flu shots, Hepatitis B vaccinations, and pneumonia vaccinations from network providers.
- Emergency services from in-network providers or from out-of-network providers.
- Urgently needed care from in-network providers or from out-of-network providers when network providers are temporarily unavailable or inaccessible, e.g., when you are temporarily outside of the plan's service area.
- Kidney dialysis services that you get at a Medicare-certified dialysis facility when you are temporarily outside the plan's service area. (If possible, please call Customer Care before you leave the service area so we can help arrange for you to have maintenance dialysis while you are away. Phone numbers for Customer Care are printed on the back cover of this booklet.)

- All covered preventive services from network providers. These services are indicated in the Chapter 4 benefits chart with an .
- Supplemental Benefits covered by the plan:
 - Health and wellness education programs – Fitness
 - Health and wellness education programs – Humana Active Outlook®
 - Nurse Advice 24 Hour Hotline (HumanaFirst®)
 - Over-the-Counter Drugs
 - Smoking Cessation (QuitNet)

Section 2.3 How to get care from specialists and other network providers

A specialist is a doctor who provides health care services for a specific disease or part of the body. There are many kinds of specialists. Here are a few examples:

- Oncologists care for patients with cancer.
- Cardiologists care for patients with heart conditions.
- Orthopedists care for patients with certain bone, joint, or muscle conditions.

When your PCP thinks that you need specialized treatment, he/she can give you a referral to see a specialist or certain other providers. If you are seeing a specialist for your care, you may need to return to your PCP for a referral for additional services.

For some types of services, your PCP may need to get approval in advance from our plan (this is called getting "prior authorization"). See Chapter 4, Section 2.1 for information about which services require prior authorization.

It is very important to get a referral (approval in advance) from your PCP before you see a specialist or certain other providers (there are a few exceptions, including women's health care that we explained earlier in this section). **If you don't have a referral (approval in advance) before you get services from a specialist, you may have to pay for these services yourself. If the specialist wants you to come back for more care, check first to be sure that the referral (approval in advance) you got from your PCP for the first visit covers more visits.**

If there are specific specialists you want to use, find out whether your PCP sends patients to these specialists. Each plan PCP has certain plan specialists they use for referrals. This means that the PCP you select may determine the specialists you may see. You may generally change your PCP at any time if you want to see a plan specialist that your current PCP can't refer you to. Earlier in this section, under "Changing your PCP," we explained how to change your PCP. If there are specific hospitals you want to use, you must first find out whether your PCP, or the doctors you will be seeing, uses these hospitals.

If you need hospital care, we will cover these services for you. Covered services are listed in the Medical Benefits Chart in Chapter 4 under the heading "Inpatient Hospital Care". We use "hospital" to mean a facility that is certified by the Medicare program and licensed by the state to provide inpatient, outpatient, diagnostic, and therapeutic services. The term "hospital" does not include facilities that mainly provide custodial care (such as convalescent nursing homes or rest homes). By "custodial care," we mean help with bathing, dressing, using the bathroom, eating, and other activities of daily living. Except in an emergency, your PCP or specialist will arrange your admission to the hospital.

For a list of network hospitals, please refer to the Provider Directory. Your doctor may not admit to all network hospitals. Please ask your doctor to find out the hospitals with which he/she has privileges.

What if a specialist or another network provider leaves our plan?

Sometimes a specialist, clinic, hospital, or other network provider you are using might leave the plan. If there is a change in your provider network, we will send you a letter notifying you of the change 30 days prior to the provider's date of termination. The notification describes the changes in your provider network and the effective date of the change. The written notification will contain specific information, depending on the type of provider that is leaving the network.

Section 2.4 How to get care from out-of-network providers

Your network PCP or plan must give you approval in advance before you can use providers not in the plan's network. This is called giving you a "referral." For more information about this and situations when you can see an out-of-network provider without a referral (such as an emergency), see Sections 2.2 and 2.3 of this chapter. If you don't have a referral (approval in advance) before you get services from an out-of-network provider, you may have to pay for these services yourself.

For some types of services, your doctor may need to get approval in advance from our plan (this is called getting "prior authorization"). See Chapter 4, Section 2.1 for more information about which services require prior authorization.

It is best to ask an out-of-network provider to bill the plan first. But, if you have already paid for the covered services, we will reimburse you for our share of the cost for covered services. Or if an out-of-network provider sends you a bill that you think we should pay, you can send it to us for payment. See Chapter 7 (Asking the plan to pay its share of a bill you have received for covered services or drugs) for information about what to do if you receive a bill or if you need to ask for reimbursement.

SECTION 3 How to get covered services when you have an emergency or an urgent need for care

Section 3.1 Getting care if you have a medical emergency

What is a "medical emergency" and what should you do if you have one?

A **"medical emergency"** is when you, or any other prudent layperson with an average knowledge of health and medicine, believe that you have medical symptoms that require immediate medical attention to prevent loss of life, loss of a limb, or loss of function of a limb. The medical symptoms may be an illness, injury, severe pain, or a medical condition that is quickly getting worse.

If you have a medical emergency:

- **Get help as quickly as possible.** Call 911 for help or go to the nearest emergency room or hospital. Call for an ambulance if you need it. You do not need to get approval or a referral first from your PCP.
- **As soon as possible, make sure that our plan has been told about your emergency.** We need to follow up on your emergency care. You or someone else should call to tell us about your emergency care, usually within 48 hours. Call your primary care physician's telephone number on the back of your ID card.

What is covered if you have a medical emergency?

You may get covered emergency medical care whenever you need it, anywhere in the United States or its territories. Our plan covers ambulance services in situations where getting to the emergency room in any other way could endanger your health. For more information, see the Medical Benefits Chart in Chapter 4 of this booklet.

You are covered for emergency care worldwide. See Chapter 4, Medical Benefits Chart (what is covered and what you pay) for more information.

If you have an emergency, we will talk with the doctors who are giving you emergency care to help manage and follow up on your care. The doctors who are giving you emergency care will decide when your condition is stable and the medical emergency is over.

After the emergency is over you are entitled to follow-up care to be sure your condition continues to be stable. Your follow-up care will be covered by our plan. If your emergency care is provided by out-of-network providers, we will try to arrange for network providers to take over your care as soon as your medical condition and the circumstances allow.

What if it wasn't a medical emergency?

Sometimes it can be hard to know if you have a medical emergency. For example, you might go in for emergency care – thinking that your health is in serious danger – and the doctor may say that it wasn't a medical emergency after all. If it turns out that it was not an emergency, as long as you reasonably thought your health was in serious danger, we will cover your care.

However, after the doctor has said that it was not an emergency, we will generally cover additional care only if you get the additional care in one of these two ways:

- You go to a network provider to get the additional care.
- – or – the additional care you get is considered "urgently needed care" and you follow the rules for getting this urgent care (for more information about this, see Section 3.2 below).

Section 3.2 Getting care when you have an urgent need for care

What is "urgently needed care"?

"Urgently needed care" is a non-emergency, unforeseen medical illness, injury, or condition that requires immediate medical care. Urgently needed care may be furnished by in-network providers or by out-of-network providers when network providers are temporarily unavailable or inaccessible. The unforeseen condition could, for example, be an unforeseen flare-up of a known condition that you have.

What if you are in the plan's service area when you have an urgent need for care?

In most situations, if you are in the plan's service area, we will cover urgently needed care only if you get this care from a network provider and follow the other rules described earlier in this chapter. However, if the circumstances are unusual or extraordinary, and network providers are temporarily unavailable or inaccessible, we will cover urgently needed care that you get from an out-of-network provider.

The plan's Provider Directory will tell you which facilities in your area are in-network. This information can also be found online at Humana.com. For any other questions regarding urgently needed care, please contact Customer Care (phone numbers are printed on the back cover of this booklet).

What if you are outside the plan's service area when you have an urgent need for care?

When you are outside the service area and cannot get care from a network provider, our plan will cover urgently needed care that you get from any provider.

Our plan does not cover urgently needed care or any other non-emergency care if you receive the care outside of the United States.

SECTION 4 What if you are billed directly for the full cost of your covered services?

Section 4.1 You can ask us to pay our share of the cost of your covered services

If you have paid more than your share for covered services, or if you have received a bill for the full cost of covered medical services, go to Chapter 7 (Asking us to pay our share of a bill you have received for covered medical services or drugs) for information about what to do.

Section 4.2 If services are not covered by our plan, you must pay the full cost

Humana Gold Plus H0108-004 (HMO) covers all medical services that are medically necessary, are listed in the plan's Medical Benefits Chart (this chart is in Chapter 4 of this booklet), and are obtained consistent with plan rules. You are responsible for paying the full cost of services that aren't covered by our plan, either because they are not plan covered services, or they were obtained out-of-network and were not authorized.

If you have any questions about whether we will pay for any medical service or care that you are considering, you have the right to ask us whether we will cover it before you get it. If we say we will not cover your services, you have the right to appeal our decision not to cover your care.

Chapter 9 (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)) has more information about what to do if you want a coverage decision from us or want to appeal a decision we have already made. You may also call Customer Care to get more information about how to do this (phone numbers are printed on the back cover of this booklet).

For covered services that have a benefit limitation, you pay the full cost of any services you get after you have used up your benefit for that type of covered service. Paying for costs once a benefit limit has been reached will **not** count toward your out-of-pocket maximum. You can call Customer Care when you want to know how much of your benefit limit you have already used.

SECTION 5 How are your medical services covered when you are in a "clinical research study"?

Section 5.1 What is a "clinical research study"?

A clinical research study (also called a "clinical trial") is a way that doctors and scientists test new types of medical care, like how well a new cancer drug works. They test new medical care procedures or drugs by asking for

volunteers to help with the study. This kind of study is one of the final stages of a research process that helps doctors and scientists see if a new approach works and if it is safe.

Not all clinical research studies are open to members of our plan. Medicare first needs to approve the research study. If you participate in a study that Medicare has not approved, you will be responsible for paying all costs for your participation in the study.

Once Medicare approves the study, someone who works on the study will contact you to explain more about the study and see if you meet the requirements set by the scientists who are running the study. You can participate in the study as long as you meet the requirements for the study and you have a full understanding and acceptance of what is involved if you participate in the study.

If you participate in a Medicare-approved study, Original Medicare pays most of the costs for the covered services you receive as part of the study. When you are in a clinical research study, you may stay enrolled in our plan and continue to get the rest of your care (the care that is not related to the study) through our plan.

If you want to participate in a Medicare-approved clinical research study, you do not need to get approval from us or your PCP. The providers that deliver your care as part of the clinical research study do not need to be part of our plan's network of providers.

Although you do not need to get our plan's permission to be in a clinical research study, **you do need to tell us before you start participating in a clinical research study.** Here is why you need to tell us:

1. We can let you know whether the clinical research study is Medicare-approved.
2. We can tell you what services you will get from clinical research study providers instead of from our plan.

If you plan on participating in a clinical research study, contact Customer Care (phone numbers are printed on the back cover of this booklet).

Section 5.2 When you participate in a clinical research study, who pays for what?

Once you join a Medicare-approved clinical research study, you are covered for routine items and services you receive as part of the study, including:

- Room and board for a hospital stay that Medicare would pay for even if you weren't in a study.
- An operation or other medical procedure if it is part of the research study.
- Treatment of side effects and complications of the new care.

Original Medicare pays most of the cost of the covered services you receive as part of the study. After Medicare has paid its share of the cost for these services, our plan will also pay for part of the costs. We will pay the difference between the cost sharing in Original Medicare and your cost sharing as a member of our plan. This means you will pay the same amount for the services you receive as part of the study as you would if you received these services from our plan.

Here's an example of how the cost sharing works: Let's say that you have a lab test that costs **\$100** as part of the research study. Let's also say that your share of the costs for this test is **\$20** under Original Medicare, but the test would be **\$10** under our plan's benefits. In this case, Original Medicare would pay **\$80** for the test and we would pay another **\$10**. This means that you would pay **\$10**, which is the same amount you would pay under our plan's benefits.

In order for us to pay for our share of the costs, you will need to submit a request for payment. With your request, you will need to send us a copy of your Medicare Summary Notices or other documentation that shows what

services you received as part of the study and how much you owe. Please see Chapter 7 for more information about submitting requests for payment.

When you are part of a clinical research study, **neither Medicare nor our plan will pay for any of the following:**

- Generally, Medicare will not pay for the new item or service that the study is testing unless Medicare would cover the item or service even if you were not in a study.
- Items and services the study gives you or any participant for free.
- Items or services provided only to collect data, and not used in your direct health care. For example, Medicare would not pay for monthly CT scans done as part of the study if your medical condition would normally require only one CT scan.

Do you want to know more?

You can get more information about joining a clinical research study by reading the publication "Medicare and Clinical Research Studies" on the Medicare website (<http://www.medicare.gov>). You can also call 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.

SECTION 6 Rules for getting care covered in a "religious non-medical health care institution"

Section 6.1 What is a religious non-medical health care institution?

A religious non-medical health care institution is a facility that provides care for a condition that would ordinarily be treated in a hospital or skilled nursing facility. If getting care in a hospital or a skilled nursing facility is against a member's religious beliefs, we will instead provide coverage for care in a religious non-medical health care institution. You may choose to pursue medical care at any time for any reason. This benefit is provided only for Part A inpatient services (non-medical health care services). Medicare will only pay for non-medical health care services provided by religious non-medical health care institutions.

Section 6.2 What care from a religious non-medical health care institution is covered by our plan?

To get care from a religious non-medical health care institution, you must sign a legal document that says you are conscientiously opposed to getting medical treatment that is "non-excepted."

- "Non-excepted" medical care or treatment is any medical care or treatment that is voluntary and not required by any federal, state, or local law.
- "Excepted" medical treatment is medical care or treatment that you get that is not voluntary or is required under federal, state, or local law.

To be covered by our plan, the care you get from a religious non-medical health care institution must meet the following conditions:

- The facility providing the care must be certified by Medicare.
- Our plan's coverage of services you receive is limited to non-religious aspects of care.
- If you get services from this institution that are provided to you in your home, our plan will cover these services only if your condition would ordinarily meet the conditions for coverage of services given by home health agencies that are not religious non-medical health care institutions.

- If you get services from this institution that are provided to you in a facility, the following conditions apply:
 - You must have a medical condition that would allow you to receive covered services for inpatient hospital care or skilled nursing facility care.
 - and – you must get approval in advance from our plan before you are admitted to the facility or your stay will not be covered.

You are covered for an unlimited number of medically necessary inpatient hospital days. See Chapter 4 (Medical Benefits Chart).

SECTION 7 Rules for ownership of durable medical equipment

Section 7.1	Will you own the durable medical equipment after making a certain number of payments under our plan?
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Durable medical equipment includes items such as oxygen equipment and supplies, wheelchairs, walkers, and hospital beds ordered by a provider for use in the home. Certain items, such as prosthetics, are always owned by the member. In this section, we discuss other types of durable medical equipment that must be rented.

In Original Medicare, people who rent certain types of durable medical equipment own the equipment after paying co-payments for the item for 13 months. As a member of Humana Gold Plus H0108-004 (HMO), however, you will not acquire ownership of rented durable medical equipment items no matter how many copayments you make for the item while a member of our plan. Under certain limited circumstances we will transfer ownership of the durable medical equipment item. Call Customer Care (phone numbers are printed on the back cover of this booklet) to find out about the requirements you must meet and the documentation you need to provide.

What happens to payments you have made for durable medical equipment if you switch to Original Medicare?

If you switch to Original Medicare after being a member of our plan: If you did not acquire ownership of the durable medical equipment item while in our plan, you will have to make 13 new consecutive payments for the item while in Original Medicare in order to acquire ownership of the item. Your previous payments while in our plan do not count toward these 13 consecutive payments.

If you made payments for the durable medical equipment item under Original Medicare before you joined our plan, these previous Original Medicare payments also do not count toward the 13 consecutive payments. You will have to make 13 consecutive payments for the item under Original Medicare in order to acquire ownership. There are no exceptions to this case when you return to Original Medicare.

Chapter 4. Medical Benefits Chart **(what is covered and what you pay)**

SECTION 1 Understanding your out-of-pocket costs for covered services

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SECTION 2 Use the Medical Benefits Chart to find out what is covered for you and how much you will pay

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SECTION 1 Understanding your out-of-pocket costs for covered services

This chapter focuses on your covered services and what you pay for your medical benefits. It includes a Medical Benefits Chart that lists your covered services and shows how much you will pay for each covered service as a member of Humana Gold Plus H0108-004 (HMO). Later in this chapter, you can find information about medical services that are not covered. Also, see exclusions and limitations pertaining to certain supplemental benefits in the chart in this chapter.

Section 1.1 Types of out-of-pocket costs you may pay for your covered services

To understand the payment information we give you in this chapter, you need to know about the types of out-of-pocket costs you may pay for your covered services.

- A **"copayment"** is the fixed amount you pay each time you receive certain medical services. You pay a copayment at the time you get the medical service. (The Medical Benefits Chart in Section 2 tells you more about your copayments.)
- **"Coinsurance"** is the percentage you pay of the total cost of certain medical services. You pay a coinsurance at the time you get the medical service. (The Medical Benefits Chart in Section 2 tells you more about your coinsurance.)

Some people qualify for state Medicaid programs to help them pay their out-of-pocket costs for Medicare. (These "Medicare Savings Programs" include the Qualified Medicare Beneficiary (QMB), Specified Low-Income Medicare Beneficiary (SLMB), Qualifying Individual (QI), and Qualified Disabled & Working Individuals (QDWI) programs.) If you are enrolled in one of these programs, you may still have to pay a copayment for the service, depending on the rules in your state.

Section 1.2 What is the most you will pay for Medicare Part A and Part B covered medical services?

Because you are enrolled in a Medicare Advantage Plan, there is a limit to how much you have to pay out-of-pocket each year for in-network medical services that are covered under Medicare Part A and Part B (see the Medical Benefits Chart in Section 2, below). This limit is called the maximum out-of-pocket amount for medical services.

As a member of Humana Gold Plus H0108-004 (HMO), the most you will have to pay out-of-pocket for in-network covered Part A and Part B services in 2014 is **\$6,700**. The amounts you pay for copayments and coinsurance for in-network covered services count toward this maximum out-of-pocket amount. (The amounts you pay for your prescription drugs, and any Supplemental Benefits (listed below) do not count toward your out-of-pocket maximum.) If you reach the maximum out-of-pocket amount of **\$6,700**, you will not have to pay any out-of-pocket costs for the rest of the year for in-network covered Part A and Part B services. However, you must continue to pay the Medicare Part B premium (unless your Part B premium is paid for you by Medicaid or another third party).

- Supplemental Benefits covered by the plan:
 - Health and wellness education programs – Fitness
 - Health and wellness education programs – Humana Active Outlook®
 - Nurse Advice 24 Hour Hotline (HumanaFirst®)

- Over-the-Counter Drugs
- Smoking Cessation (QuitNet)

Section 1.3 Our plan does not allow providers to "balance bill" you

As a member of Humana Gold Plus H0108-004 (HMO), an important protection for you is that you only have to pay the plan's cost-sharing amount when you get services covered by our plan. We do not allow providers to add additional separate charges, called "balance billing." This protection (that you never pay more than your cost-sharing amount) applies even if we pay the provider less than the provider charges for a service and even if there is a dispute and we don't pay certain provider charges.

Here is how this protection works.

- If your cost sharing is a copayment (a set amount of dollars, for example, **\$15.00**), then you pay only that amount for any covered services from a network provider.
- If your cost sharing is a coinsurance (a percentage of the total charges), then you never pay more than that percentage. However, your cost depends on which type of provider you see:
 - > If you receive the covered services from a network provider, you pay the coinsurance percentage multiplied by the plan's reimbursement rate (as determined in the contract between the provider and the plan).
 - > If you receive the covered services from an out-of-network provider who participates with Medicare, you pay the coinsurance percentage multiplied by the Medicare payment rate for participating providers. (Remember, the plan covers services from out-of-network providers only in certain situations, such as when you get a referral.)
 - > If you receive the covered services from an out-of-network provider who does not participate with Medicare, you pay the coinsurance percentage multiplied by the Medicare payment rate for non-participating providers. (Remember, the plan covers services from out-of-network providers only in certain situations, such as when you get a referral.)

SECTION 2 Use the Medical Benefits Chart to find out what is covered for you and how much you will pay

Section 2.1 Your medical benefits and costs as a member of the plan

The Medical Benefits Chart on the following pages lists the services Humana Gold Plus H0108-004 (HMO) covers and what you pay out-of-pocket for each service. The services listed in the Medical Benefits Chart are covered only when the following coverage requirements are met:

- Your Medicare-covered services must be provided according to the coverage guidelines established by Medicare.
- Your services (including medical care, services, supplies, and equipment) must be medically necessary. "Medically necessary" means that the services, supplies, or drugs are needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.
- You receive your care from a network provider. In most cases, care you receive from an out-of-network provider will not be covered. Chapter 3 provides more information about requirements for using network providers and the situations when we will cover services from an out-of-network provider.
- You have a primary care physician (a PCP) who is providing and overseeing your care. In most situations, your PCP must give you approval in advance before you can see other providers in the plan's network. This is called

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)


giving you a "referral." Chapter 3 provides more information about getting a referral and the situations when you do not need a referral.

- Some of the services listed in the Medical Benefits Chart are covered only if your doctor or other network provider gets approval in advance (sometimes called "prior authorization") from us. Covered services that need approval in advance are marked in the Medical Benefits Chart by a footnote. In addition, the following services not listed in the Benefits Chart require prior authorization:
 - Automatic Implantable Cardioverter Defibrillators (AICD)
 - Pain Management Procedures
 - Hyperbaric Therapy
 - Infertility Testing and Treatment
 - Varicose Vein: Surgical Treatment and Sclerotherapy
 - Ventricular Assist Devices
 - Routine Maternity Care
 - Cardiac Implants
 - Sleep Studies
 - Transthoracic Echocardiogram (TTE)
 - Coronary Angioplasty/Stent Procedures
 - Bone Growth Stimulators
 - Spinal Fusion



Other important things to know about our coverage:


- Like all Medicare health plans, we cover everything that Original Medicare covers. For some of these benefits, you pay more in our plan than you would in Original Medicare. For others, you pay less. (If you want to know more about the coverage and costs of Original Medicare, look in your Medicare & You 2014 Handbook. View it online at <http://www.medicare.gov> or ask for a copy by calling 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.)
- For all preventive services that are covered at no cost under Original Medicare, we also cover the service at no cost to you. However, if you also are treated or monitored for an existing medical condition during the visit when you receive the preventive service, a copayment will apply for the care received for the existing medical condition.
- Sometimes, Medicare adds coverage under Original Medicare for new services during the year. If Medicare adds coverage for any services during 2014, either Medicare or our plan will cover those services.




 You will see this apple next to the preventive services in the benefits chart.

Medical Benefits Chart	
Services that are covered for you	What you must pay when you get these services
 Abdominal aortic aneurysm screening A one-time screening ultrasound for people at risk. The plan only covers this screening if you get a referral for it as a result of your "Welcome to Medicare" preventive visit.	<ul style="list-style-type: none"> • If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for



2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)



Services that are covered for you	What you must pay when you get these services
	<p>the existing medical condition or other services will also apply.</p> <p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment for an abdominal aortic aneurysm screening in a specialist's office.• \$0 copayment for an abdominal aortic aneurysm screening in a freestanding radiological facility.• \$0 copayment for an abdominal aortic aneurysm screening in an outpatient hospital.
<p>Ambulance services</p> <ul style="list-style-type: none">• Covered ambulance services include fixed wing, rotary wing, and ground ambulance services, to the nearest appropriate facility that can provide care only if they are furnished to a member whose medical condition is such that other means of transportation are contraindicated (could endanger the person's health) or if authorized by the plan.• Non-emergency transportation by ambulance is appropriate if it is documented that the member's condition is such that other means of transportation are contraindicated (could endanger the person's health) and that transportation by ambulance is medically required.	<p><u>In Network:</u></p> <ul style="list-style-type: none">• \$200 copayment per date of service for ambulance services regardless of the number of trips.
<p> Annual wellness visit</p> <p>If you've had Part B for longer than 12 months, you can get an annual wellness visit to develop or update a personalized prevention plan based on your current health and risk factors. This is covered once every 12 months.</p> <ul style="list-style-type: none">• Note: Your first annual wellness visit can't take place within 12 months of your "Welcome to Medicare" preventive visit. However, you don't need to have had a "Welcome to Medicare" visit to be covered for annual wellness visits after you've had Part B for 12 months.• Note: Any lab or diagnostic procedures that are ordered are not covered under this benefit and you pay your plan cost sharing amount for those services separately.	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none">• There is no coinsurance, copayment, or deductible for the annual wellness visit.
<p> Bone mass measurement</p>	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the

Services that are covered for you	What you must pay when you get these services
<p>For qualified individuals (generally, this means people at risk of losing bone mass or at risk of osteoporosis), the following services are covered every 24 months or more frequently if medically necessary: procedures to identify bone mass, detect bone loss, or determine bone quality, including a physician's interpretation of the results.</p>	<p>visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply.</p> <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for bone mass measurement in a specialist's office. • \$0 copayment for bone mass measurement in a freestanding radiological facility. • \$0 copayment for bone mass measurement in an outpatient hospital.
<p> Breast cancer screening (mammograms)</p> <p>Covered services include:</p> <ul style="list-style-type: none"> • One baseline mammogram between the ages of 35 and 39 • One screening mammogram every 12 months for women age 40 and older • Clinical breast exams once every 24 months 	<ul style="list-style-type: none"> • If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for a screening mammogram in a specialist's office. • \$0 copayment for a screening mammogram in a freestanding radiological facility. • \$0 copayment for a screening mammogram in an outpatient hospital.
<p>Cardiac rehabilitation services</p> <p>Comprehensive programs of cardiac rehabilitation services that include exercise, education, and counseling are covered for members who meet certain conditions with a doctor's referral. The plan also covers intensive</p>	<p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$5 copayment for cardiac rehabilitation in a specialist's office.

Services that are covered for you	What you must pay when you get these services
cardiac rehabilitation programs that are typically more rigorous or more intense than cardiac rehabilitation programs.	<ul style="list-style-type: none"> • \$30 copayment for cardiac rehabilitation in an outpatient hospital.
<p> Cardiovascular disease risk reduction visit (therapy for cardiovascular disease)</p> <p>We cover 1 visit per year with your primary care doctor to help lower your risk for cardiovascular disease. During this visit, your doctor may discuss aspirin use (if appropriate), check your blood pressure, and give you tips to make sure you're eating well.</p>	<ul style="list-style-type: none"> • If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for the cardiovascular disease reduction visit.
<p> Cardiovascular disease testing</p> <p>Blood tests for the detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) once every 5 years (60 months).</p>	<ul style="list-style-type: none"> • If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for services in a primary care physician's office. • \$0 copayment for services in a specialist's office. • \$0 copayment for services in a freestanding laboratory facility. • \$0 copayment for services in an outpatient hospital.
<p> Cervical and vaginal cancer screening</p> <p>Covered services include:</p> <ul style="list-style-type: none"> • For all women: Pap tests and pelvic exams are covered once every 24 months 	<ul style="list-style-type: none"> • If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to

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Services that are covered for you	What you must pay when you get these services
<ul style="list-style-type: none">If you are at high risk of cervical cancer or have had an abnormal Pap test and are of childbearing age: one Pap test every 12 months	<p>the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply.</p> <p><u>In Network:</u></p> <ul style="list-style-type: none">\$0 copayment for services in a primary care physician's office.\$0 copayment for services in a specialist's office.
<p>Chiropractic services</p> <p>Covered services include:</p> <ul style="list-style-type: none">We cover only manual manipulation of the spine to correct subluxationOther services performed by a chiropractor are not covered	<p><u>In Network:</u></p> <ul style="list-style-type: none">\$5 copayment for Medicare covered chiropractic services in a specialist's office.
<p> Colorectal cancer screening</p> <p>For people 50 and older, the following are covered:</p> <ul style="list-style-type: none">Flexible sigmoidoscopy (or screening barium enema as an alternative) every 48 monthsFecal occult blood test, every 12 months <p>For people at high risk of colorectal cancer, we cover:</p> <ul style="list-style-type: none">Screening colonoscopy (or screening barium enema as an alternative) every 24 months <p>For people not at high risk of colorectal cancer, we cover:</p> <ul style="list-style-type: none">Screening colonoscopy every 10 years (120 months), but not within 48 months of a screening sigmoidoscopy	<ul style="list-style-type: none">If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none">\$0 copayment for colorectal screening exams in a specialist's office.\$0 copayment for colorectal screening exams in an ambulatory surgical center.\$0 copayment for colorectal screening exams in an outpatient hospital.
<p> Depression screening</p> <p>We cover 1 screening for depression per year. The screening must be done in a primary care setting that can provide follow-up treatment and referrals.</p>	<ul style="list-style-type: none">If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for


Services that are covered for you	What you must pay when you get these services
	<p>the existing medical condition or other services will also apply.</p> <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for the depression screening.
<p> Diabetes screening</p> <p>We cover this screening (includes fasting glucose tests) if you have any of the following risk factors: high blood pressure (hypertension), history of abnormal cholesterol and triglyceride levels (dyslipidemia), obesity, or a history of high blood sugar (glucose). Tests may also be covered if you meet other requirements, like being overweight and having a family history of diabetes.</p> <p>Based on the results of these tests, you may be eligible for up to two diabetes screenings every 12 months.</p>	<ul style="list-style-type: none"> • If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for diabetes screening in a primary care physician's office. • \$0 copayment for diabetes screening in a specialist's office. • \$0 copayment for diabetes screening in a freestanding laboratory facility. • \$0 copayment for diabetes screening in an outpatient hospital.
<p> Diabetes self-management training, diabetic services and supplies</p> <p>For all people who have diabetes (insulin and non-insulin users). Covered services include:</p> <ul style="list-style-type: none"> • Supplies to monitor your blood glucose: Blood glucose monitor, blood glucose test strips, lancet devices and lancets, and glucose-control solutions for checking the accuracy of test strips and monitors • For people with diabetes who have severe diabetic foot disease: One pair per calendar year of therapeutic custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts, or one pair of depth shoes and three pairs of inserts (not including the non-customized removable inserts provided with such shoes). Coverage includes fitting. • Diabetes self-management training is covered under certain conditions 	<p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for diabetes self-management training in a primary care physician's office. • \$0 copayment for diabetes self-management training in a specialist's office. • \$0 copayment for diabetes self-management training in an outpatient hospital. • 0% coinsurance for diabetic monitoring supplies from a preferred durable medical equipment provider. • 20% coinsurance for diabetic monitoring supplies from a

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	<p>non-preferred durable medical equipment provider.</p> <ul style="list-style-type: none">• 0% coinsurance for diabetic shoes and inserts.• 10% coinsurance for a 30-day supply of Accu-Check and Onetouch diabetic monitoring supplies from a network retail pharmacy.• 20% coinsurance for a 30-day supply of all other diabetic monitoring supplies from a network retail pharmacy.
<p>Durable medical equipment and related supplies</p> <p>(For a definition of "durable medical equipment," see Chapter 12 of this booklet.)</p> <p>Covered items include, but are not limited to: wheelchairs, crutches, hospital bed, IV infusion pump, oxygen equipment, nebulizer, and walker.</p> <p>We cover all medically necessary durable medical equipment covered by Original Medicare. If our supplier in your area does not carry a particular brand or manufacturer, you may ask them if they can special order it for you.</p> <ul style="list-style-type: none">• Prior authorization may be required for home health services. Contact the plan for details.	<p><u>In Network:</u></p> <ul style="list-style-type: none">• 20% coinsurance for durable medical equipment.
<p>Emergency care</p> <p>Emergency care refers to services that are:</p> <ul style="list-style-type: none">• Furnished by a provider qualified to furnish emergency services, and• Needed to evaluate or stabilize an emergency medical condition. <p>A medical emergency is when you, or any other prudent layperson with an average knowledge of health and medicine, believe that you have medical symptoms that require immediate medical attention to prevent loss of life, loss of a limb, or loss of function of a limb. The medical symptoms may be an illness, injury, severe pain, or a medical condition that is quickly getting worse.</p> <p>You are covered for emergency care world-wide. If you have an emergency outside of the U.S. and its territories, you will be responsible to pay for the services rendered upfront. You must submit to Humana for reimbursement, for more information please see Chapter 7. We may not reimburse you for all out of pocket expenses. This is because our</p>	<ul style="list-style-type: none">• You do not pay the emergency room visit costshare if you are admitted to the hospital within 24 hours for the same condition. <p><u>In Network:</u></p> <ul style="list-style-type: none">• \$65 copayment for emergency services in an emergency room.• If you receive emergency care at an out-of-network hospital and need inpatient care after your emergency condition is stabilized, you must return to a network hospital in order for your care to continue to be covered OR you must have your inpatient care at the out-of-network hospital

Services that are covered for you	What you must pay when you get these services
contracted rates may be lower than providers outside of the U.S. and its territories.	authorized by the plan and your cost is the cost-sharing you would pay at a network hospital.
<p>Health and wellness education programs</p> <p>Fitness</p> <p>Get fit with Humana Fitness from the SilverSneakers® Fitness Program.</p> <p>With this benefit, you are covered for everything included with a membership* at participating fitness centers across the country.</p> <p>Your benefit also includes:</p> <ul style="list-style-type: none"> • SilverSneakers classes designed exclusively for older adults to improve your body's strength and flexibility • On-site advisors to act as your contact for information and personalized service • Social activities and health education events • Access to www.silversneakers.com, where you can create exercise and nutrition plans, track fitness progress, find health articles and recipes, and more. • SilverSneakers® Steps personalized home fitness program <p>* Any nonstandard fitness center services that usually have an extra fee are not included in your membership.</p>	<p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment
<p>Health and wellness education programs</p> <p>Humana Active Outlook®</p> <p>Learn to live a healthier, more fulfilled life with the award-winning Humana Active Outlook Program. No matter what your personal health goals are, this health and wellness education program can help. There's no extra cost to you.</p> <ul style="list-style-type: none"> • Discover new things in HAO Magazine, health tracking materials, and HAO Digest, with practical tips for those living with chronic conditions • Learn from custom health and wellness information and interactive tools at HumanaActiveOutlook.com • Find support for healthy changes with programs from Humana: <ul style="list-style-type: none"> – Work toward wellness with Humana personal health coaching – Learn to live better with personalized health support for chronic health conditions 	<p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment
Hearing services	

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<p>Diagnostic hearing and balance evaluations performed by your PCP to determine if you need medical treatment are covered as outpatient care when furnished by a physician, audiologist, or other qualified provider.</p>	<p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment for services in a primary care physician's office.• \$5 copayment for services in a specialist's office.
<p> HIV screening</p> <p>For people who ask for an HIV screening test or who are at increased risk for HIV infection, we cover:</p> <ul style="list-style-type: none">• One screening exam every 12 months <p>For women who are pregnant, we cover:</p> <ul style="list-style-type: none">• Up to three screening exams during a pregnancy	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment for an HIV screening in a primary care physician's office.• \$0 copayment for an HIV screening in a specialist's office.• \$0 copayment for an HIV screening in an outpatient hospital.• \$0 copayment for an HIV screening in a freestanding laboratory facility.
<p>Home health agency care</p> <p>Prior to receiving home health services, a doctor must certify that you need home health services and will order home health services to be provided by a home health agency. You must be homebound, which means leaving home is a major effort.</p> <p>Covered services include, but are not limited to:</p> <ul style="list-style-type: none">• Part-time or intermittent skilled nursing and home health aide services (To be covered under the home health care benefit, your skilled nursing and home health aide services combined must total fewer than 8 hours per day and 35 hours per week)• Physical therapy, occupational therapy, and speech therapy• Medical and social services	<p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment for each home health visit.

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Services that are covered for you	What you must pay when you get these services
<ul style="list-style-type: none">• Medical equipment and supplies• Prior authorization may be required for home health services. Contact the plan for details.	
<p>Hospice care</p> <p>You may receive care from any Medicare-certified hospice program. Your hospice doctor can be a network provider or an out-of-network provider. Covered services include:</p> <ul style="list-style-type: none">• Drugs for symptom control and pain relief• Short-term respite care• Home care <p><u>For hospice services and for services that are covered by Medicare Part A or B and are related to your terminal condition:</u> Original Medicare (rather than our plan) will pay for your hospice services and any Part A and Part B services related to your terminal condition. While you are in the hospice program, your hospice provider will bill Original Medicare for the services that Original Medicare pays for.</p> <p><u>For services that are covered by Medicare Part A or B and are not related to your terminal condition:</u> If you need non-emergency, non-urgently needed services that are covered under Medicare Part A or B and that are not related to your terminal condition, your cost for these services depends on whether you use a provider in our plan's network:</p> <ul style="list-style-type: none">• If you obtain the covered services from a network provider, you only pay the plan cost-sharing amount for in-network services• If you obtain the covered services from an out-of-network provider, you pay the cost sharing under Fee-For-Service Medicare (Original Medicare) <p><u>For services that are covered by Humana Gold Plus H0108-004 (HMO) but are not covered by Medicare Part A or B:</u> Humana Gold Plus H0108-004 (HMO) will continue to cover plan-covered services that are not covered under Part A or B whether or not they are related to your terminal condition. You pay your plan cost sharing amount for these services.</p> <p>Note: If you need non-hospice care (care that is not related to your terminal condition), you should contact us to arrange the services. Getting your non-hospice care through our network providers will lower your share of the costs for the services.</p> <p>Our plan covers hospice consultation services (one time only) for a terminally ill person who hasn't elected the hospice benefit.</p>	<p>When you enroll in a Medicare-certified hospice program, your hospice services and your Part A and Part B services related to your terminal condition are paid for by Original Medicare, not Humana Gold Plus H0108-004 (HMO).</p>
 Immunizations	<ul style="list-style-type: none">• If you also are treated or monitored for an existing

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Services that are covered for you	What you must pay when you get these services
<p>Covered Medicare Part B services include:</p> <ul style="list-style-type: none"> • Pneumonia vaccine • Flu shots, once a year in the fall or winter • Hepatitis B vaccine if you are at high or intermediate risk of getting Hepatitis B • Other vaccines if you are at risk and they meet Medicare Part B coverage rules • We also cover some vaccines under our outpatient prescription drug benefit 	<p>medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply.</p> <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for immunizations in a primary care physician's office. • \$0 copayment for immunizations in a specialist's office.
<p>Inpatient hospital care</p> <p>You are covered for an unlimited number of medically necessary days. Covered services include but are not limited to:</p> <ul style="list-style-type: none"> • Semi-private room (or a private room if medically necessary) • Meals including special diets • Regular nursing services • Costs of special care units (such as intensive care or coronary care units) • Drugs and medications • Lab tests • X-rays and other radiology services • Necessary surgical and medical supplies • Use of appliances, such as wheelchairs • Operating and recovery room costs • Physical, occupational, and speech language therapy • Inpatient substance abuse services • Under certain conditions, the following types of transplants are covered: corneal, kidney, kidney-pancreatic, heart, liver, lung, heart/lung, bone marrow, stem cell, and intestinal/multivisceral. If you need a transplant, we will arrange to have your case reviewed by a Medicare-approved transplant center that will decide whether you are a candidate for a transplant. Transplant providers may be local or outside of the service area. If local transplant providers are willing to accept the Original Medicare rate, then you can choose to obtain your transplant services locally or at a distant location offered by the plan. If Humana Gold Plus H0108-004 (HMO) provides transplant services at a distant location (outside of the service area) and you chose to obtain transplants at this distant location, we will arrange or pay for appropriate lodging and transportation costs for you and a companion. Travel reimbursement 	<p><u>In Network:</u></p> <ul style="list-style-type: none"> • Your inpatient benefits will begin on day one each time you are admitted or transferred to a specific facility type, including Inpatient Rehabilitation facilities, Long Term Acute Care (LTAC) facilities, Inpatient Acute Care facilities, and Inpatient Psychiatric facilities. • \$335 copayment per day, days 1 to 5 for inpatient care in an inpatient hospital • \$0 copayment for physician services in an inpatient hospital.

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<p>requires a minimum of 100 miles one way to transplant center and is limited to \$10,000 per transplant.</p> <ul style="list-style-type: none">– If you are in need of a solid organ or bone marrow/stem cell transplant, please contact our Transplant Department at 1-866-421-5663 for important information about your transplant care.• Blood - including storage and administration. Coverage of whole blood and packed red cells begins with the first pint of blood that you need.• Physician services <p>Note: To be an inpatient, your provider must write an order to admit you formally as an inpatient of the hospital. Even if you stay in the hospital overnight, you might still be considered an "outpatient." If you are not sure if you are an inpatient or an outpatient, you should ask the hospital staff.</p> <p>You can also find more information in a Medicare fact sheet called "Are You a Hospital Inpatient or Outpatient? If You Have Medicare – Ask!" This fact sheet is available on the Web at http://www.medicare.gov/Publications/Pubs/pdf/11435.pdf or by calling 1-800-MEDICARE (1-800-633-4227). TTY users call 1-877-486-2048. You can call these numbers for free, 24 hours a day, 7 days a week.</p> <ul style="list-style-type: none">• Prior authorization is required for inpatient hospital care• Prior authorization is required for transplant services.	
<p>Inpatient mental health care</p> <ul style="list-style-type: none">• Covered services include mental health care services that require a hospital stay.• 190-day lifetime limit for inpatient services in a psychiatric hospital.<ul style="list-style-type: none">– The 190-day limit does not apply to Mental Health services provided in a psychiatric unit of a general hospital.• The benefit days used under the Original Medicare program will count toward the 190-day lifetime reserve days when enrolling in a Medicare Advantage plan.• Prior authorization is required for inpatient mental health care.	<p><u>In Network:</u></p> <ul style="list-style-type: none">• Your inpatient benefits will begin on day one each time you are admitted or transferred to a specific facility type, including Inpatient Rehabilitation facilities, Long Term Acute Care (LTAC) facilities, Inpatient Acute Care facilities, and Inpatient Psychiatric facilities.• \$335 copayment per day, days 1 to 5 for inpatient mental health care in an inpatient hospital• \$296 copayment per day, days 1 to 5 for inpatient mental health care in an inpatient psychiatric facility• \$0 copayment for physician services in an inpatient hospital.• \$0 copayment for physician services in an inpatient psychiatric facility.

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<p>Inpatient services covered during a non-covered inpatient stay</p> <p>If you have exhausted your inpatient benefits or if the inpatient stay is not reasonable and necessary, we will not cover your inpatient stay. However, in some cases, we will cover certain services you receive while you are in the hospital or the skilled nursing facility (SNF). Covered services include, but are not limited to:</p> <ul style="list-style-type: none">• Physician services• Diagnostic tests (like lab tests)• X-ray, radium, and isotope therapy including technician materials and services• Surgical dressings• Splints, casts and other devices used to reduce fractures and dislocations• Prosthetics and orthotics devices (other than dental) that replace all or part of an internal body organ (including contiguous tissue), or all or part of the function of a permanently inoperative or malfunctioning internal body organ, including replacement or repairs of such devices• Leg, arm, back, and neck braces; trusses, and artificial legs, arms, and eyes including adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient's physical condition• Physical therapy, speech therapy, and occupational therapy	<p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment for physician services in an inpatient hospital.• \$0 copayment for physician services in a Skilled Nursing Facility.
<p> Medical nutrition therapy</p> <p>This benefit is for people with diabetes, renal (kidney) disease (but not on dialysis), or after a kidney transplant when referred by your doctor.</p> <p>We cover 3 hours of one-on-one counseling services during your first year that you receive medical nutrition therapy services under Medicare (this includes our plan, any other Medicare Advantage plan, or Original Medicare), and 2 hours each year after that. If your condition, treatment, or diagnosis changes, you may be able to receive more hours of treatment with a physician's referral. A physician must prescribe these services and renew their referral yearly if your treatment is needed into the next calendar year.</p>	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment for nutrition therapy in a primary care physician's office.• \$0 copayment for nutrition therapy in a specialist's office.• \$0 copayment for nutrition therapy in an outpatient hospital.
Medicare Part B prescription drugs	<u>In Network:</u>

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<p>These drugs are covered under Part B of Original Medicare. Members of our plan receive coverage for these drugs through our plan. Covered drugs include:</p> <ul style="list-style-type: none">• Drugs that usually aren't self-administered by the patient and are injected or infused while you are getting physician, hospital outpatient, or ambulatory surgical center services• Drugs you take using durable medical equipment (such as nebulizers) that were authorized by the plan• Clotting factors you give yourself by injection if you have hemophilia• Immunosuppressive Drugs, if you were enrolled in Medicare Part A at the time of the organ transplant• Injectable osteoporosis drugs, if you are homebound, have a bone fracture that a doctor certifies was related to post-menopausal osteoporosis, and cannot self-administer the drug• Antigens• Certain oral anti-cancer drugs and anti-nausea drugs• Certain drugs for home dialysis, including heparin, the antidote for heparin when medically necessary, topical anesthetics, and erythropoiesis-stimulating agents (such as Epogen®, Procrit®, Epoetin Alfa, Aranesp®, or Darbepoetin Alfa)• Intravenous Immune Globulin for the home treatment of primary immune deficiency diseases• Prior authorization may be required for Part B drugs. Contact plan for details. <p>Chapter 5 explains the Part D prescription drug benefit, including the rules you must follow to have prescriptions covered. What you pay for your Part D prescription drugs through our plan is listed in Chapter 6.</p>	<ul style="list-style-type: none">• 20% coinsurance for Medicare Part B covered drugs in a physician's office.• \$200 copayment for Medicare Part B covered drugs administered in an outpatient hospital• 20% coinsurance for chemotherapy drugs in a physician's office.• 20% coinsurance for chemotherapy drugs in an outpatient hospital.• 20% coinsurance for Medicare Part B covered drugs from a network retail pharmacy.
<p>Nurse Advice 24 Hour Hotline (HumanaFirst®)</p> <p>If you have questions about symptoms you're experiencing but aren't sure if you need to see your doctor, Humana can help. Call HumanaFirst, our advice line for members, 24 hours a day, seven days a week at 1-800-622-9529 (TTY 711). It's staffed by nurses who can help address your immediate health concerns and answer questions about particular medical conditions.</p>	<p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment
<p> Obesity screening and therapy to promote sustained weight loss</p> <p>If you have a body mass index of 30 or more, we cover intensive counseling to help you lose weight. This counseling is covered if you get it in a primary care setting, where it can be coordinated with your comprehensive prevention plan. Talk to your primary care doctor or practitioner to find out more.</p>	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for

Services that are covered for you	What you must pay when you get these services
	<p>the existing medical condition or other services will also apply.</p> <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for obesity screening and therapy in a primary care physician's office.
<p>Outpatient diagnostic tests and therapeutic services and supplies</p> <p>Covered services include, but are not limited to:</p> <ul style="list-style-type: none"> • X-rays • Radiation (radium and isotope) therapy including technician materials and supplies • Surgical supplies, such as dressings • Splints, casts and other devices used to reduce fractures and dislocations • Laboratory tests • Blood. Coverage begins with the first pint of blood that you need. Coverage of storage and administration begins with the first pint of blood that you need. • Other outpatient diagnostic tests • Prior authorization is required for CT scans, MRA, MRI, nuclear stress test, PET scans, PET registry (NOPR), SPECT, Molecular Diagnostic/Genetic Testing, radiation therapy, and outpatient observation. 	<p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for services in a primary care physician's office. • \$5 copayment for services in a specialist's office. <ul style="list-style-type: none"> – 20% coinsurance for radiation therapy in a specialist's office. – \$200 copayment for a facility based sleep study in a specialist's office. • \$200 copayment for services in an outpatient hospital. <ul style="list-style-type: none"> – \$335 copayment for advanced imaging services in an outpatient hospital. – \$335 copayment for nuclear medicine services in an outpatient hospital. – 20% coinsurance for radiation therapy in an outpatient hospital. – \$0 copayment for laboratory services in an outpatient hospital. • \$0 copayment for a home based sleep study. • \$200 copayment for services in a freestanding radiological facility. <ul style="list-style-type: none"> – \$285 copayment for advanced imaging services in a freestanding radiological facility. – \$285 copayment for nuclear medicine services in a freestanding radiological facility.

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Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you	What you must pay when you get these services
	<ul style="list-style-type: none"> – 20% coinsurance for radiation therapy in a freestanding radiological facility. • \$0 copayment for laboratory services in a freestanding laboratory facility. • 20% coinsurance for medical supplies. • There may be additional Part B drugs or injectables received in conjunction with these services, please see "Medicare Covered Part B Drugs" within this chart for a description of those benefits.
<p>Outpatient hospital services</p> <p>We cover medically-necessary services you get in the outpatient department of a hospital for diagnosis or treatment of an illness or injury.</p> <p>Covered services include, but are not limited to:</p> <ul style="list-style-type: none"> • Services in an emergency department or outpatient clinic, such as observation services or outpatient surgery • Laboratory and diagnostic tests billed by the hospital • Mental health care, including care in a partial-hospitalization program, if a doctor certifies that inpatient treatment would be required without it • X-rays and other radiology services billed by the hospital • Medical supplies such as splints and casts • Certain screenings and preventive services • Certain drugs and biologicals that you can't give yourself <p>Note: Unless the provider has written an order to admit you as an inpatient to the hospital, you are an outpatient and pay the cost-sharing amounts for outpatient hospital services. Even if you stay in the hospital overnight, you might still be considered an "outpatient." If you are not sure if you are an outpatient, you should ask the hospital staff.</p> <p>You can also find more information in a Medicare fact sheet called "Are You a Hospital Inpatient or Outpatient? If You Have Medicare – Ask!" This fact sheet is available on the Web at http://www.medicare.gov/Publications/Pubs/pdf/11435.pdf or by calling 1-800-MEDICARE (1-800-633-4227). TTY users call 1-877-486-2048. You can call these numbers for free, 24 hours a day, 7 days a week.</p>	<p>In Network:</p> <ul style="list-style-type: none"> • \$200 copayment for services in an outpatient hospital. <ul style="list-style-type: none"> – \$335 copayment for advanced imaging services in an outpatient hospital. – \$335 copayment for nuclear medicine services in an outpatient hospital. – 20% coinsurance for radiation therapy in an outpatient hospital. – \$0 copayment for laboratory services in an outpatient hospital. – \$335 copayment for surgery services in an outpatient hospital. – \$55 copayment for each partial hospitalization visit • \$65 copayment for emergency services in an emergency room. • \$5 copayment for clinic services.


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Services that are covered for you	What you must pay when you get these services
<ul style="list-style-type: none">Prior authorization is required for CT scans, MRA, MRI, nuclear stress test, PET scans, PET registry (NOPR), SPECT, Molecular Diagnostic/Genetic Testing, and outpatient observation.	
Outpatient mental health care Covered services include: Mental health services provided by a state-licensed psychiatrist or doctor, clinical psychologist, clinical social worker, clinical nurse specialist, nurse practitioner, physician assistant, or other Medicare-qualified mental health care professional as allowed under applicable state laws.	<u>In Network:</u> <ul style="list-style-type: none">\$5 copayment for mental health services in a specialist's office.\$200 copayment for mental health services in an outpatient hospital.
Outpatient rehabilitation services Covered services include: physical therapy, occupational therapy, and speech language therapy. Outpatient rehabilitation services are provided in various outpatient settings, such as hospital outpatient departments, independent therapist offices, and Comprehensive Outpatient Rehabilitation Facilities (CORFs). <ul style="list-style-type: none">Prior authorization is required for physical, occupational, and speech therapies.	<u>In Network:</u> <ul style="list-style-type: none">\$30 copayment for services in a specialist's office.\$30 copayment for services in an outpatient hospital.\$30 copayment for physical therapy in a Comprehensive Outpatient Rehabilitation Facility.\$30 copayment for occupational therapy in a Comprehensive Outpatient Rehabilitation Facility.\$30 copayment for speech therapy in a Comprehensive Outpatient Rehabilitation Facility.
Outpatient substance abuse services	<u>In Network:</u> <ul style="list-style-type: none">\$5 copayment for substance abuse services in a specialist's office.\$200 copayment for substance abuse services in an outpatient hospital.\$55 copayment for each partial hospitalization visit.
Outpatient surgery, including services provided at hospital outpatient facilities and ambulatory surgical centers Note: If you are having surgery in a hospital facility, you should check with your provider about whether you will be an inpatient or outpatient. Unless the provider writes an order to admit you as an inpatient to the hospital,	<u>In Network:</u> <ul style="list-style-type: none">\$335 copayment for surgery services in an outpatient hospital.

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Services that are covered for you	What you must pay when you get these services
<p>you are an outpatient and pay the cost-sharing amounts for outpatient surgery. Even if you stay in the hospital overnight, you might still be considered an "outpatient."</p> <ul style="list-style-type: none">• Prior authorization is required for abdominoplasty, balloon sinuplasty, blepharoplasty, breast procedures, otoplasty, elective outpatient cardiac catheterizations, penile implant, rhinoplasty, septoplasty, obesity, oral surgeries, and surgery for obstructive sleep apnea.	<ul style="list-style-type: none">• \$285 copayment for surgery services in an ambulatory surgical center.• \$0 copayment for surgeon services in an outpatient hospital.• \$0 copayment for surgeon services in an ambulatory surgical center.
<p>Over-the-Counter Drugs</p> <p>You are eligible for a \$10 monthly benefit to be used toward the purchase of over-the-counter (OTC) health and wellness products available through our mail order service. The order form can be obtained by calling Customer Care.</p>	<p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment
<p>Partial hospitalization services</p> <p>"Partial hospitalization" is a structured program of active psychiatric treatment provided in a hospital outpatient setting or by a community mental health center, that is more intense than the care received in your doctor's or therapist's office and is an alternative to inpatient hospitalization.</p> <ul style="list-style-type: none">• Prior authorization is required for partial hospitalization services.	<p><u>In Network:</u></p> <ul style="list-style-type: none">• \$55 copayment for each partial hospitalization visit.
<p>Physical Exam (Routine)</p> <p>In addition to the Annual Wellness Visit or the "Welcome to Medicare" physical exam, you are covered for the following exam once per year:</p> <ul style="list-style-type: none">• Comprehensive preventive medicine evaluation and management, including an age and gender appropriate history, examination, and counseling/anticipatory guidance/risk factor reduction interventions• Note: Any lab or diagnostic procedures that are ordered are not covered under this benefit and you pay your plan cost sharing amount for those services separately.	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment for a comprehensive routine physical exam in a primary care physician's office.
<p>Physician/Practitioner services, including doctor's office visits</p> <p>Covered services include:</p>	<p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment for each visit in a primary care physician's office.

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Services that are covered for you	What you must pay when you get these services
<ul style="list-style-type: none">• Medically-necessary medical care or surgery services furnished in a physician's office, certified ambulatory surgical center, hospital outpatient department, or any other location• Consultation, diagnosis, and treatment by a specialist• Basic hearing and balance exams performed by your PCP or specialist, if your doctor orders it to see if you need medical treatment.• Certain telehealth services including consultation, diagnosis, and treatment by a physician or practitioner for patients in certain rural areas or other locations approved by Medicare• Second opinion by another network provider prior to surgery• Non-routine dental care (covered services are limited to surgery of the jaw or related structures, setting fractures of the jaw or facial bones, extraction of teeth to prepare the jaw for radiation treatments of neoplastic cancer disease, or services that would be covered when provided by a physician)	<ul style="list-style-type: none">• \$5 copayment for each visit in a specialist's office.<ul style="list-style-type: none">– 20% coinsurance for radiation therapy in a specialist's office.
Podiatry services Covered services include: <ul style="list-style-type: none">• Diagnosis and the medical or surgical treatment of injuries and diseases of the feet (such as hammer toe or heel spurs).• Routine foot care for members with certain medical conditions affecting the lower limbs	<u>In Network:</u> <ul style="list-style-type: none">• \$5 copayment for Medicare covered podiatry services in a specialist's office.
 Prostate cancer screening exams For men age 50 and older, covered services include the following - once every 12 months: <ul style="list-style-type: none">• Digital rectal exam• Prostate Specific Antigen (PSA) test	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <u>In Network:</u> <ul style="list-style-type: none">• \$0 copayment for prostate cancer screening exam in a primary care physician's office.• \$0 copayment for prostate cancer screening exam in a specialist's office.
Prosthetic devices and related supplies	<u>In Network:</u> <ul style="list-style-type: none">• 20% coinsurance for prosthetics.

Services that are covered for you	What you must pay when you get these services
<p>Devices (other than dental) that replace all or part of a body part or function. These include, but are not limited to: colostomy bags and supplies directly related to colostomy care, pacemakers, braces, prosthetic shoes, artificial limbs, and breast prostheses (including a surgical brassiere after a mastectomy). Includes certain supplies related to prosthetic devices, and repair and/or replacement of prosthetic devices. Also includes some coverage following cataract removal or cataract surgery – see "Vision Care" later in this section for more detail.</p> <ul style="list-style-type: none">• Prior authorization is required for prosthetic devices.	
<p>Pulmonary rehabilitation services</p> <p>Comprehensive programs of pulmonary rehabilitation are covered for members who have moderate to very severe chronic obstructive pulmonary disease (COPD) and a referral for pulmonary rehabilitation from the doctor treating the chronic respiratory disease.</p>	<p><u>In Network:</u></p> <ul style="list-style-type: none">• \$5 copayment for pulmonary rehabilitation in a specialist's office.• \$30 copayment for pulmonary rehabilitation in an outpatient hospital.
<p> Screening and counseling to reduce alcohol misuse</p> <p>We cover one alcohol misuse screening for adults with Medicare (including pregnant women) who misuse alcohol, but aren't alcohol dependent.</p> <p>If you screen positive for alcohol misuse, you can get up to 4 brief face-to-face counseling sessions per year (if you're competent and alert during counseling) provided by a qualified primary care doctor or practitioner in a primary care setting.</p>	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p><u>In Network:</u></p> <ul style="list-style-type: none">• \$0 copayment for an alcohol misuse screening or counseling session.
<p> Screening for sexually transmitted infections (STIs) and counseling to prevent STIs</p> <p>We cover sexually transmitted infection (STI) screenings for chlamydia, gonorrhea, syphilis, and Hepatitis B. These screenings are covered for pregnant women and for certain people who are at increased risk for an STI when the tests are ordered by a primary care provider. We cover these tests once every 12 months or at certain times during pregnancy.</p> <p>We also cover up to 2 individual 20 to 30 minute, face-to-face high-intensity behavioral counseling sessions each year for sexually active</p>	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply.

Services that are covered for you	What you must pay when you get these services
adults at increased risk for STIs. We will only cover these counseling sessions as a preventive service if they are provided by a primary care provider and take place in a primary care setting, such as a doctor's office.	<u>In Network:</u> <ul style="list-style-type: none"> • \$0 copayment for an STI screening or counseling session.
Services to treat kidney disease and conditions Covered services include: <ul style="list-style-type: none"> • Kidney disease education services to teach kidney care and help members make informed decisions about their care. For members with stage IV chronic kidney disease when referred by their doctor, we cover up to six sessions of kidney disease education services per lifetime. • Outpatient dialysis treatments (including dialysis treatments when temporarily out of the service area, as explained in Chapter 3) • Inpatient dialysis treatments (if you are admitted as an inpatient to a hospital for special care) • Self-dialysis training (includes training for you and anyone helping you with your home dialysis treatments) • Home dialysis equipment and supplies • Certain home support services (such as, when necessary, visits by trained dialysis workers to check on your home dialysis, to help in emergencies, and check your dialysis equipment and water supply) Certain drugs for dialysis are covered under your Medicare Part B drug benefit. For information about coverage for Part B Drugs, please go to the section, "Medicare Part B prescription drugs."	<u>In Network:</u> <ul style="list-style-type: none"> • \$0 copayment for kidney disease education services in a primary care physician's office. • \$0 copayment for kidney disease education services in a specialist's office. • 0% coinsurance for renal dialysis services in a dialysis center. • 20% coinsurance for renal dialysis services in an outpatient hospital. • 20% coinsurance for dialysis equipment. • \$0 copayment for each home health visit in a member's home. • For inpatient renal dialysis services, please see "Inpatient hospital care" earlier in this section.
Skilled nursing facility (SNF) care (For a definition of "skilled nursing facility care," see Chapter 12 of this booklet. Skilled nursing facilities are sometimes called "SNFs.") You are covered for up to 100 medically necessary days per benefit period. Prior hospital stay is not required. Covered services include but are not limited to: <ul style="list-style-type: none"> • Semiprivate room (or a private room if medically necessary) • Meals, including special diets • Skilled nursing services • Physical therapy, occupational therapy, and speech therapy • Drugs administered to you as part of your plan of care (This includes substances that are naturally present in the body, such as blood clotting factors.) • Blood - including storage and administration. Coverage of whole blood and packed red cells begins with the first pint of blood you need. • Medical and surgical supplies ordinarily provided by SNFs • Laboratory tests ordinarily provided by SNFs • X-rays and other radiology services ordinarily provided by SNFs 	<ul style="list-style-type: none"> • A new skilled nursing benefit period will begin on day one when you first enroll in a Humana Medicare Advantage plan, or you have been discharged from a skilled nursing facility (or not received inpatient skilled level of care) for 60 consecutive days. <u>In Network:</u> Per benefit period, you pay: <ul style="list-style-type: none"> • \$25 copayment per day, days 1 to 20 for skilled nursing care in a Skilled Nursing Facility • \$150 copayment per day, days 21 to 100 for skilled nursing care in a Skilled Nursing Facility

Services that are covered for you	What you must pay when you get these services
<ul style="list-style-type: none"> • Use of appliances such as wheelchairs ordinarily provided by SNFs • Physician/Practitioner services <p>Generally, you will get your SNF care from network facilities. However, under certain conditions listed below, you may be able to pay in-network cost sharing for a facility that isn't a network provider, if the facility accepts our plan's amounts for payment.</p> <ul style="list-style-type: none"> • A nursing home or continuing care retirement community where you were living right before you went to the hospital (as long as it provides skilled nursing facility care). • A SNF where your spouse is living at the time you leave the hospital. • Prior authorization is required for inpatient skilled nursing care. 	
<p> Smoking and tobacco use cessation (counseling to stop smoking or tobacco use)</p> <p><u>If you use tobacco, but do not have signs or symptoms of tobacco-related disease:</u> We cover two counseling quit attempts within a 12-month period as a preventive service with no cost to you from an in-network provider. Each counseling attempt includes up to four face-to-face visits.</p> <p><u>If you use tobacco and have been diagnosed with a tobacco-related disease or are taking medicine that may be affected by tobacco:</u> We cover cessation counseling services. We cover two counseling quit attempts within a 12-month period, however, you will pay the applicable inpatient or outpatient cost sharing. Each counseling attempt includes up to four face-to-face visits.</p>	<ul style="list-style-type: none"> • If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply. <p>If you use tobacco, but do not have signs or symptoms of tobacco-related disease:</p> <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for smoking cessation services in a primary care physician's office. • \$0 copayment for smoking cessation services in a specialist's office. <p>If you use tobacco and have been diagnosed with a tobacco-related disease or are taking medicine that may be affected by tobacco:</p> <p><u>In Network:</u></p> <ul style="list-style-type: none"> • \$0 copayment for smoking cessation services in a primary care physician's office. • \$5 copayment for smoking cessation services in a specialist's office.

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Services that are covered for you	What you must pay when you get these services
Smoking Cessation (QuitNet) Stop smoking with QuitNet Comprehensive. Services include: <ul style="list-style-type: none">• Web-based or telephonic coaching• The QuitNet, QuitGuide, and QuitTips e-mail support• Over-the-counter nicotine replacement therapy, including patches, gums, and lozenges You can enroll by phone at 1-888-572-4074 or online at www.quitnet.com/humana .	<u>In Network:</u> <ul style="list-style-type: none">• \$0 copayment
Urgently needed care Urgently needed care is care provided to treat a non-emergency, unforeseen medical illness, injury, or condition that requires immediate medical care. Urgently needed care may be furnished by in-network providers or by out-of-network providers when network providers are temporarily unavailable or inaccessible. You are covered for urgently needed care in the United States and its territories.	<u>In Network:</u> <ul style="list-style-type: none">• \$0 copayment for urgently needed care in a primary care physician's office.• \$5 copayment for urgently needed care in a specialist's office.• \$5 copayment for urgently needed care in an immediate care facility.
 Vision care Covered services include: <ul style="list-style-type: none">• Outpatient physician services for the diagnosis and treatment of diseases and injuries of the eye, including treatment for age-related macular degeneration. Original Medicare doesn't cover routine eye exams (eye refractions) for eyeglasses/contacts.• One pair of eyeglasses or contact lenses after each cataract surgery that includes insertion of an intraocular lens. (If you have two separate cataract operations, you cannot reserve the benefit after the first surgery and purchase two eyeglasses after the second surgery.) Corrective lenses/frames (and replacements) needed after a cataract removal without a lens implant.	<u>In Network:</u> <ul style="list-style-type: none">• \$5 copayment for Medicare covered vision services in a specialist's office.• \$0 copayment for Medicare covered eyewear following cataract surgery.
 "Welcome to Medicare" Preventive Visit The plan covers the one-time "Welcome to Medicare" preventive visit. The visit includes a review of your health, as well as education and counseling about the preventive services you need (including certain screenings and shots), and referrals for other care if needed. Important: We cover the "Welcome to Medicare" preventive visit only within the first 12 months you have Medicare Part B. When you make your	<ul style="list-style-type: none">• If you also are treated or monitored for an existing medical condition during the visit when you receive a preventive service, or if other services are billed in addition to the preventive service, the cost sharing for the care received for the existing medical condition or other services will also apply.

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Services that are covered for you	What you must pay when you get these services
<p>appointment, let your doctor's office know you would like to schedule your "Welcome to Medicare" preventive visit.</p> <ul style="list-style-type: none">• Note: Any lab or diagnostic procedures that are ordered are not covered under this benefit and you pay your plan cost sharing amount for those services separately.	<p><u>In Network:</u></p> <ul style="list-style-type: none">• There is no coinsurance, copayment, or deductible for the Welcome to Medicare preventive visit.

Section 2.2 Extra "optional supplemental" benefits you can buy

Your plan offers some extra benefits that are not covered by Original Medicare and are not included in your benefits package as a plan member. These extra benefits are called "**Optional Supplemental Benefits**." If you want these optional supplemental benefits, you must sign up for them and you may have to pay an extra premium for them. The optional supplemental benefits included in this section are subject to the same appeals process as any other plan benefits.

If you purchase these optional supplemental benefits, this Evidence of Coverage contract will apply to the extra benefits you purchase. There are multiple ways to pay the premium for the optional supplemental benefits, including payments by check, credit or debit card, or automatic withdrawal from your checking or savings account. For more information about your payment options, please call Customer Care at the phone number on the back of your Humana member ID card.

Services that are covered for you

What you must pay

Optional Supplemental Benefits

Extra benefits you can add to customize your Medicare Advantage plan

Optional supplemental benefits enrollment

To get optional supplemental benefits, you must choose the benefits in one of two ways:

1. Enroll in optional supplemental benefits (OSBs) when you enroll in your Medicare Advantage plan. In most cases, your optional supplemental benefits will begin the same day that your Medicare Advantage plan begins.
2. Fill out a separate optional supplemental benefits enrollment application at any time. You can also call 1-800-645-7322 (TTY: 711), Monday - Friday, 8 a.m. to 8 p.m. local time. If you enroll this way, your optional supplemental benefits will begin on the first day of the month after Humana receives your application.

Medicare Advantage plans and optional supplemental benefits must be reapproved by the Centers for Medicare & Medicaid Services (CMS) each year. Any changes to your plan will be reported to you in the Annual Notification of Changes letter sent in the fall. Once your plan is approved, if you do not change your Medicare Advantage plan during the annual election period and you are enrolled in an OSB, then your OSB will be renewed automatically at the beginning of the next year, if the OSB is still available.

Please note the following benefits are purchased separately and are not included in your Medicare Advantage plan premium. These benefits are offered on an annual basis. Any unused benefits will not "roll over" to the next coverage year.

Services that are covered for you

What you must pay

For more information about enrollment in optional supplemental benefits, call Customer Care at the phone number on the back of your Humana member ID card. That number also appears at the end of this section.

Optional supplemental benefits provider directory

To find a provider for your optional supplemental benefits (OSB), see your OSB Provider Directory. It will be sent to you within 10 days of enrolling in an OSB.

If you need an OSB Provider Directory or want the name of a provider, please call Customer Care. Humana is not responsible for the availability or ongoing participation of any provider and the provider availability may change. Always make sure your provider is in the network before receiving care.

Optional supplemental benefits voluntary disenrollment

If you want to end your optional supplemental benefits coverage, you need to let us know by writing us a letter. We **cannot** accept disenrollment requests by phone.

Your letter should:

- Tell us clearly that you want to disenroll from the optional supplemental benefits only – not the Medicare Advantage plan
- Include your name, member ID number, and signature
- Be sent to the Humana disenrollment office. You can get the address by calling Customer Care at the phone number on the back of your Humana member ID card. The number is also at the end of this section.

Services that are covered for you	What you must pay
Optional supplemental benefits involuntary disenrollment	
<p>If you do not pay the premiums for your optional supplemental benefits, you will lose your OSB coverage. We will tell you in writing that you have 60 days to pay the optional supplemental benefit premium before your coverage ends. At the end of your grace period, we will end the benefits if you have not paid everything you owe.</p> <p>If you end these benefits, or if you lose them because you did not pay what you owe, you can start these benefits again later in the year. Any claims that were previously processed in the original coverage will count towards your benefit maximum. Your benefits will not start over.</p>	
Refund of premium	
<p>If you pay more premiums than you owe, we may return these funds if you ask to end the benefits. If we issue a refund for overpayment, it will be mailed within 45 business days of notification. However, if you have an outstanding balance for your Medicare Advantage (MA) plan premium, we will apply your overpayment of optional supplemental benefit premiums to your outstanding balance for your Medicare Advantage plan.</p>	
MyOptionSM Dental – High PPO	
<p>This optional supplemental benefit (OSB) provides you with extra benefits. You will need to pay extra monthly premiums for these benefits. These benefits include coverage for many preventive, basic, and major dental services.</p>	
Premium information	
Monthly premium	\$25.30 monthly benefit premium.
Coverage information	
<u>General information</u>	
<ul style="list-style-type: none"> Individual annual deductible – annual deductible does not apply to preventive and diagnostic services Maximum plan benefit – combined for both in-network and out-of-network services – of \$1,500 per person per calendar year 	\$50 annual deductible.

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Services that are covered for you	What you must pay
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Dental benefit	
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With this optional supplemental benefit, you are covered for certain diagnostic and preventive services – including bitewing X-rays, routine cleanings, and checkups – when you see a network dentist. You can choose to see a non-network dentist for covered dental services. Humana negotiates rates for dental services. When you see a non-network dentist, you will pay your part of the negotiated rate (your coinsurance). If your dentist charges more than that rate, you may have to pay more.

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)

Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you	What you must pay	
Covered dental services – total annual benefit (Medicare Advantage Plan plus OSB)	Network Dentist*	Non-Network Dentist**
Preventive and diagnostic dental services <ul style="list-style-type: none">Oral examinations – two per calendar yearBitewing X-rays – one series of films per calendar yearDental prophylaxis (cleanings) – two per calendar year	0%	30%
Basic dental services (minor restorative) <ul style="list-style-type: none">Amalgam restorations (fillings) and composite resin restorations (fillings) – two from this group per calendar year<ul style="list-style-type: none">Anterior (front) teeth – amalgam restorations and composite resin restorationsPosterior (back) teeth – amalgam restorations and comparable amalgam benefit applied for composite resin restorations. Member is responsible for remaining cost difference between composite restoration and amalgam restoration.Extractions – two per calendar yearCrown or bridge re-cement – one per calendar yearEmergency treatment for pain – two per calendar yearPeriodontal scaling and root planing – one procedure per quadrant every three years	50%	55%
Major dental services (endodontics, periodontics, and oral surgery) <ul style="list-style-type: none">Root canal treatment – one per calendar yearCrowns – one per calendar yearComplete dentures – one complete upper and/or lower complete denture every five yearsPartial dentures – one per calendar yearDenture adjustments (not covered within six months of initial placement) – one per calendar yearDenture reline (Not allowed on spare dentures) – one per calendar year	70%	75%

*Network dentists have agreed to provide services at an in-network rate. If you see a network dentist, you cannot be billed more than the in-network rate.

**Non-network dentists have not agreed to provide services at an in-network rate. Humana negotiates rates for dental services. When you see a non-network dentist, you will pay your part of the negotiated rate (your coinsurance). If your dentist charges more than that rate, you may have to pay more.

Services that are covered for you	What you must pay
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General benefit payments	
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The optional supplemental benefit helps you pay for covered dental services, as shown in the Coverage Information section. Covered dental services are subject to the conditions, limitations, exclusions, and maximums of this optional supplemental benefit.

After you receive a dental service, we will check to see if it is a covered dental service. If we determine it is a covered dental service, we will pay benefits as follows:

1. We will determine the total covered expense.
2. We will review the covered expense against any maximum benefits that may apply.
3. We will check to see if you have met your deductible. If you have not, we will subtract any amount needed to meet the deductible.
4. We will pay the remaining eligible covered expense to you or your dentist, based on your coinsurance for that covered service.

Alternate services

If there are two or more services that can fix a dental condition, Humana will decide how to pay your benefits using the covered expenses for the least expensive covered service that produces a professionally satisfactory result, as determined by us. We will pay up to the reimbursement limit for the least expensive covered service and subject to any deductible, coinsurance, and maximum benefit. You must pay the excess amount.

If you or your dentist choose a treatment that costs more than the one we recommend, Humana's payment will be based on the cost of the less expensive treatment. You will be responsible for the rest of the bill.

Pretreatment plan

We suggest that if dental care you need is expected to exceed **\$300**, you or your dentist send a dental treatment plan for us to review before your treatment. The dental treatment plan should include:

1. A list of services you will receive. Your dentist should use the American Dental Association nomenclature and codes;
2. Your dentist's written description of the proposed treatment;
3. Supporting pretreatment X-rays showing your dental needs;
4. Itemized cost of the proposed treatment; and
5. Any other appropriate diagnostic materials that we may request.

An estimate for services is not a guarantee of what we will pay. It tells you and your dentist in advance about the benefits payable for the covered expenses in the treatment plan. We will notify you and your dentist of the benefits payable based on the submitted treatment plan.

An estimate for services is not necessary for emergency care.

Services that are covered for you	What you must pay
Process and timing	
An estimate for services is valid for 90 days after the date we notify you and your dentist of the benefits payable for the proposed treatment plan. This is subject to your eligibility of coverage. If treatment will not begin for more than 90 days after the date we notify you and your dentist, we recommend that you submit a new treatment plan.	
General provisions	
Dentists are independent providers. Humana's obligations are limited to payment for services described in this document.	
Dental records. We have access to dental and treatment records of members. We use this information for determination of benefits, processing claims, utilization review, quality assurance, financial audit, or for any other purposes reasonably related to covered dental services. Each member should fill out and send us such additional consents, releases, and other documents we may ask for in order to determine or provide benefits. If we do not get all of the information we need from you and your dentist, we can decide not to pay benefits for your treatment.	
Limitations and exclusions	
This MyOption Dental – High PPO optional supplemental benefit does not include coverage for the following:	
<ol style="list-style-type: none"> Any expenses incurred while you qualify for any workers' compensation or occupational disease act or law, whether or not you applied for coverage. Services that are: <ol style="list-style-type: none"> Free or that you would not be required to pay for if you did not have this insurance, unless charges are received from and reimbursable to the U.S. government or any of its agencies as required by law; Furnished by, or payable under, any plan or law through any government or any political subdivision – this does not include Medicare or Medicaid; or Furnished by any U.S. government-owned or operated hospital/institution/agency for any service connected with sickness or bodily injury. Any loss caused or contributed by: war or any act of war, whether declared or not; any act of international armed conflict; or any conflict involving armed forces of any international authority. Any expense arising from the completion of forms. Your failure to keep an appointment with the dentist. Any service we consider cosmetic dentistry unless it is necessary as a result of an accidental injury sustained while you are covered under this policy. We consider the following cosmetic dentistry procedures: <ol style="list-style-type: none"> Facings on crowns or pontics – the portion of a fixed bridge between the abutments – posterior to the second bicuspid 	

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you	What you must pay
Limitations and exclusions	
<ul style="list-style-type: none"> b. Any service to correct congenital malformation c. Any service performed primarily to improve appearance; or characterization and personalization of prosthetic devices 7. Charges for: any type of implant and all related services, including crowns or the prosthetic device attached to it; precision or semi-precision attachments; overdentures and any endodontic treatment associated with overdentures; other customized attachments. 8. Any service related to: <ul style="list-style-type: none"> a. Altering vertical dimension of teeth b. Restoration or maintenance of occlusion c. Splinting teeth, including multiple abutments, or any service to stabilize periodontally weakened teeth d. Replacing tooth structures lost as a result of abrasion, attrition, erosion, or abfraction e. Bite registration or bite analysis 9. Infection control, including but not limited to sterilization techniques. 10. Fees for treatment performed by someone other than a dentist except for scaling and teeth cleaning, and the topical application of fluoride that can be performed by a licensed dental hygienist. The treatment must be rendered under the supervision and guidance of the dentist in accordance with generally accepted dental standards. 11. Any hospital, surgical, or treatment facility, or for services of an anesthesiologist or anesthesiologist. 12. Prescription drugs or pre-medications, whether dispensed or prescribed. 13. Any service not specifically listed in the coverage information. 14. Any service that we determine: Is not a dental necessity; does not offer a favorable prognosis; does not have uniform professional endorsement; or is deemed to be experimental or investigational in nature. 15. Orthodontic services. 16. Any expense incurred before your effective date or after the date your coverage under this optional supplemental benefit terminates. 17. Services provided by someone who ordinarily lives in your home or who is a family member. 18. Charges exceeding the reimbursement limit for the service. 19. Treatment resulting from any intentionally self-inflicted injury or bodily illness. 20. Local anesthetics, irrigation, nitrous oxide, bases, pulp caps, temporary dental services, study models, treatment plans, occlusal adjustments, or tissue preparation associated with the impression or placement of a restoration when charged as a separate service. These services are considered an integral part of the entire dental service. 21. Repair and replacement of orthodontic appliances. 	

Services that are covered for you	What you must pay
Limitations and exclusions	
<p>22. Any surgical or nonsurgical treatment for any jaw joint problems, including any temporomandibular joint disorder, craniomaxillary, craniomandibular disorder, or other conditions of the joint linking the jaw bone and skull; or treatment of the facial muscles used in expression and chewing functions, for symptoms including, but not limited to, headaches.</p> <p>23. Extractions, except for extractions of erupted tooth or exposed root (includes routine removal of tooth structure, minor smoothing of socket bone, and closure, as necessary), or surgical removal of erupted tooth requiring elevation of mucoperiosteal flap and removal of bone of section of tooth.</p>	
Excess coverage	
<p>We will not pay benefits for any accidental injury if other insurance will provide payments or expense coverage, regardless of whether the other coverage is described as primary, excess, or contingent. If your claim against another insurer is denied or partially paid, we will process your claim according to the terms and conditions of this certificate. If we make a payment, you agree to assign to us any right you have against the other insurer for dental expenses <u>we</u> pay. Payments made by the other insurer will be credited toward any applicable coinsurance or calendar year deductibles.</p> <p>It's your responsibility to understand your dental coverage, including its limitations and exclusions. To be covered, all dental services must be received from a licensed dentist who deems the service necessary and must be approved by the plan. Remember, the greatest savings on covered services are through OSB network dentists. The dentist you choose may ask you to sign an informed consent document detailing the risks, covered dental services, and options to all recommended treatments. You should always ask the dentist for a treatment plan detailing the services to be performed and the associated costs prior to having work performed.</p>	
Questions?	
<p>For more information about MyOption Dental – High PPO or to request an optional supplemental benefit application, call HumanaDental Customer Care at 1-800-669-6614. For TTY, call 711. Monday – Friday, 8 a.m. – 6 p.m. local time.</p> <p>Visit Humana.com</p>	

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you		What you must pay
MyOptionSM Vision		
This optional supplemental benefit (OSB) provides you with extra benefits. You will need to pay extra monthly premiums for these benefits. These benefits include coverage for a routine eye exam for members who wear eyeglasses, as well as one set of eyeglass frames and one pair of lenses, and/or contact lenses.		
Premium information		
Monthly premium		\$15.30 monthly benefit premium.
Coverage information		
<u>Vision benefit through EyeMed Vision Care</u>		
<ul style="list-style-type: none"> The MyOption Vision optional supplemental benefit includes coverage for a routine eye exam for members who wear eyeglasses and standard lenses as follows: 		

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you	What you must pay	
Covered vision benefits	EyeMed Network Vision Provider	Non-EyeMed Network Vision Provider
<ul style="list-style-type: none"> Routine exam for members who wear eyeglasses with refraction/dilation as necessary 	\$40 allowance*	\$40 allowance
*Visit any in-network EyeMed Select vision provider and your routine exam charge will not exceed the \$40 allowance.		
<ul style="list-style-type: none"> One set of eyeglass frames and one pair of lenses and/or contact lenses (conventional or disposable lenses). Eyeglass lens treatments to include polycarbonate, UV, scratch resistance and transitional tinting. The benefit can only be used one time. Any remaining benefit dollars do not "roll over" to a future purchase. 	\$350 benefit	\$350 (combined in and out-of-network)
Frequency		
<ul style="list-style-type: none"> Routine examination – Once every 12 months One set of eyeglass frames and one pair of lenses and/or contact lenses (conventional or disposable) – Once every 12 months 		

Services that are covered for you

What you must pay

Choosing a vision provider

You may choose to get vision care from either an EyeMed vision provider or a non-EyeMed vision provider. Choosing an EyeMed vision provider from the OSB Provider Directory will decrease your costs for vision OSB services.

- To find a provider for your optional supplemental benefits, see your OSB Provider Directory. It will be sent to you within 10 days of enrolling in an OSB.
- If you do not receive an OSB Provider Directory or need help finding an EyeMed provider, please call EyeMed at the phone number at the end of this document. To get the in-network rate, make sure your provider is in the EyeMed Select network before you get care. We are not responsible for the availability or ongoing participation of any provider.

If you choose an EyeMed vision provider, just call the provider's office and make an appointment. Be sure to tell the provider's office that you are a Humana Medicare Advantage member **with EyeMed benefits**. If you have questions about EyeMed vision providers in your area or any other questions about your vision coverage under MyOption Vision, please call EyeMed at the phone number at the end of this document.

If you choose to get vision care from a non-EyeMed vision provider, you will have to pay the full bill at the time of your appointment. Then you will submit an EyeMed out-of-network claim form. The out-of-network claim form can be found on MyHumana by clicking on Vision Information. You must also send an itemized statement of charges to EyeMed Vision Care.

Whether you choose an EyeMed vision provider or a non-EyeMed vision provider, you must pay for any copayment and any costs and fees that exceed your covered vision benefit allowance, and any services or materials that are not covered under MyOption Vision.

How to submit a paper claim

If you receive emergency services or other services from a non-network provider, you will have to pay the full cost of those services and then submit claims documentation. Within 90 days, call EyeMed at the phone number at the end of this document to request a claim form and instructions on submitting your claim. The out-of-network claim form can also be found on MyHumana by clicking on Vision Information.

General provisions

EyeMed Vision Care is a third party administrator and an independent provider offering retail and private practitioners.

Humana's obligations are limited to payment for services described in this document.

Services that are covered for you	What you must pay
Limitations and exclusions	
<p>The MyOption Vision optional supplemental benefit does not include coverage for the following:</p> <ol style="list-style-type: none"> 1. Standard contact lens fit and follow-up. 2. Refitting or change in lens design after initial fitting. 3. No more than one set of eyeglass frames and one pair of lenses per calendar year. 4. The benefit dollars can only be used one time. Any remaining benefit dollars do not "roll over" to a future purchase. 5. Any expense arising from the completion of forms. 6. Any service not specifically listed in your optional supplemental benefit. 7. Orthoptic or vision training. 8. Subnormal vision aids and associated testing. 9. Aniseikonic lenses. 10. Any service we consider cosmetic. 11. Any expense incurred before your effective date or after the date your coverage under this optional supplemental benefit terminates. 12. Services provided by someone who ordinarily lives in your home or who is a family member. 13. Charges exceeding the allowance for the service. 14. Treatment resulting from any intentionally self-inflicted injury or bodily illness. 15. Plano lenses. 16. Medical or surgical treatment of eye, eyes, or supporting structures. 17. Non-prescription sunglasses. 18. Two pair of glasses in lieu of bifocals. 19. Services or materials provided by any other group benefit plans providing vision care. 20. Certain name brands when manufacturer imposes no discount. 21. Corrective vision treatment of an experimental nature. 22. Solutions and/or cleaning products for glasses or contact lenses. 23. Non-prescription items. 24. Costs associated with securing materials. 25. Pre- and post-operative services. 26. Orthokeratology. 27. Routine maintenance of materials. 28. Artistically painted lenses. 29. Any expenses incurred while you qualify for any workers' compensation or occupational disease act or law, whether or not you applied for coverage. 30. Services that are: <ol style="list-style-type: none"> a. Free or that you would not be required to pay for if you did not have this insurance, unless charges are received from and reimbursable to the U.S. government or any of its agencies as required by law; 	

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you

What you must pay

Limitations and exclusions

- b. Furnished by, or payable under, any plan or law through any government or any political subdivision (this does not include Medicare or Medicaid); or
- c. Furnished by any U.S. government-owned or operated hospital/institution/agency for any service connected with sickness or bodily injury.
- 31. Any loss caused or contributed by: war or any act of war, whether declared or not; any act of international armed conflict; or any conflict involving armed forces of any international authority.
- 32. Your failure to keep an appointment.
- 33. Any hospital, surgical or treatment facility, or for services of an anesthesiologist or anesthesiologist.
- 34. Prescription drugs or pre-medications, whether dispensed or prescribed.
- 35. Any service that we determine is not a visual necessity; does not offer a favorable prognosis; does not have uniform professional endorsement; or is deemed to be experimental or investigational in nature.
- 36. Replacement of lenses or eyeglass frames furnished under this optional supplemental benefit which are lost or broken, unless otherwise available under the optional supplemental benefit.
- 37. Any examination or material required by an employer as a condition of employment or safety eyewear.
- 38. Pathological treatment.

Questions?

To request an optional supplemental benefit application,
call Humana Customer Care at
1-800-457-4708
For TTY, call 711

Seven days a week, 8 a.m. – 8 p.m. local time

Please note that our automated phone system may answer during weekends and holidays from February 15 – September 30. Please leave your name and telephone number, and we will call you back by the end of the next business day.

For information on vision benefits,
call EyeMed Customer Service at
1-888-289-0595
For TTY, call 711

Monday – Saturday, 7:30 a.m. – 11 p.m. Eastern time
Sunday, 11 a.m. – 8 p.m. Eastern time

Visit **Humana.com**

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you		What you must pay
MyOptionSM Plus		
This optional supplemental benefit provides you with extra benefits. You will need to pay extra monthly premiums for these benefits. These benefits include both dental and vision. This document will explain all the details of your dental benefits, and then it will cover your vision benefits.		
Premium information		
Monthly premium		\$24.30 monthly benefit premium.
Coverage information		
<u>General information</u>		
<ul style="list-style-type: none"> Individual annual deductible – annual deductible does not apply to preventive and diagnostic services Maximum plan benefit – combined for both in-network and out-of-network services – of \$1,000 per person per calendar year on dental coverage. 		\$50 annual deductible on dental coverage.
Dental benefit		
<p>With this optional supplemental benefit, you are covered for certain diagnostic and preventive services – including bitewing X-rays, routine cleanings, and checkups – when you see a network dentist. You can choose to see a non-network dentist for covered dental services. Humana negotiates rates for dental services. When you see a non-network dentist, you will pay your part of the negotiated rate (your coinsurance). If your dentist charges more than that rate, you may have to pay more.</p>		

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you	What you must pay	
	Network Dentist*	Non-Network Dentist**
Covered dental services – total annual benefit (Medicare Advantage Plan plus OSB)		
Preventive and diagnostic dental services		
<ul style="list-style-type: none">Oral examinations – two per calendar yearBitewing X-rays – one series of films per calendar yearDental prophylaxis (cleanings) – two per calendar year	0%	30%
Basic dental services (minor restorative)		
<ul style="list-style-type: none">Amalgam restorations (fillings) and composite resin restorations (fillings) – two from this group per calendar year<ul style="list-style-type: none">Anterior (front) teeth – amalgam restorations and composite resin restorationsPosterior (back) teeth – amalgam restorations and comparable amalgam benefit applied for composite resin restorations. Member is responsible for remaining cost difference between composite restoration and amalgam restoration.Extractions – two per calendar yearCrown or bridge re-cement – one per calendar yearEmergency treatment for pain – two per calendar year	50%	55%

*Network dentists have agreed to provide services at an in-network rate. If you see a network dentist, you cannot be billed more than the in-network rate.

**Non-network dentists have not agreed to provide services at an in-network rate. Humana negotiates rates for dental services. When you see a non-network dentist, you will pay your part of the negotiated rate (your coinsurance). If your dentist charges more than that rate, you may have to pay more.

General benefit payments

The optional supplemental benefit helps you pay for covered dental services, as shown in the Coverage Information section. Covered dental services are subject to the conditions, limitations, exclusions, and maximums of this optional supplemental benefit.

After you receive a dental service, we will check to see if it is a covered dental service. If we determine it is a covered dental service, we will pay benefits as follows:

1. We will determine the total covered expense.
2. We will review the covered expense against any maximum benefits that may apply.
3. We will check to see if you have met your deductible. If you have not, we will subtract any amount needed to meet the deductible.
4. We will pay the remaining eligible covered expense to you or your dentist, based on your coinsurance for that covered service.

Services that are covered for you

What you must pay

Alternate services

If there are two or more services that can fix a dental condition, Humana will decide how to pay your benefits using the covered expenses for the least expensive covered service that produces a professionally satisfactory result, as determined by us. We will pay up to the reimbursement limit for the least expensive covered service and subject to any deductible, coinsurance, and maximum benefit. You must pay the excess amount.

If you or your dentist choose a treatment that costs more than the one we recommend, Humana's payment will be based on the cost of the less expensive treatment. You will be responsible for the rest of the bill.

Pretreatment plan

We suggest that if dental care you need is expected to exceed **\$300**, you or your dentist send a dental treatment plan for us to review before your treatment. The dental treatment plan should include:

1. A list of services you will receive. Your dentist should use the American Dental Association nomenclature and codes;
2. Your dentist's written description of the proposed treatment;
3. Supporting pretreatment X-rays showing your dental needs;
4. Itemized cost of the proposed treatment; and
5. Any other appropriate diagnostic materials that we may request.

An estimate for services is not a guarantee of what we will pay. It tells you and your dentist in advance about the benefits payable for the covered expenses in the treatment plan. We will notify you and your dentist of the benefits payable based on the submitted treatment plan.

An estimate for services is not necessary for emergency care.

Process and timing

An estimate for services is valid for 90 days after the date we notify you and your dentist of the benefits payable for the proposed treatment plan. This is subject to your eligibility of coverage. If treatment will not begin for more than 90 days after the date we notify you and your dentist, we recommend that you submit a new treatment plan.

Services that are covered for you

What you must pay

General provisions

Dentists are independent providers. Humana's obligations are limited to payment for services described in this document.

Dental records. We have access to dental and treatment records of members. We use this information for determination of benefits, processing claims, utilization review, quality assurance, financial audit, or for any other purpose reasonably related to covered dental services. Each member should fill out and send us such additional consents, releases, and other documents we may ask for in order to determine or provide benefits. If we do not get all of the information we need from you and your dentist, we can decide not to pay benefits for your treatment.

Dental limitations and exclusions

This MyOption Plus optional supplemental benefit does not include coverage for the following:

1. Any expenses incurred while you qualify for any workers' compensation or occupational disease act or law, whether or not you applied for coverage.
2. Services that are:
 - a. Free or that you would not be required to pay for if you did not have this insurance, unless charges are received from and reimbursable to the U.S. government or any of its agencies as required by law
 - b. Furnished by, or payable under, any plan or law through any government or any political subdivision – this does not include Medicare or Medicaid; or
 - c. Furnished by any U.S. government-owned or operated hospital/institution/agency for any service connected with sickness or bodily injury.
3. Any loss caused or contributed by: war or any act of war, whether declared or not; any act of international armed conflict; or any conflict involving armed forces of any international authority.
4. Any expense arising from the completion of forms.
5. Your failure to keep an appointment with the dentist.
6. Any service we consider cosmetic dentistry unless it is necessary as a result of an accidental injury sustained while you are covered under this policy. We consider the following cosmetic dentistry procedures:
 - a. Facings on crowns or pontics – the portion of a fixed bridge between the abutments – posterior to the second bicuspid
 - b. Any service to correct congenital malformation
 - c. Any service performed primarily to improve appearance; or characterization and personalization of prosthetic devices
7. Charges for: any type of implant and all related services, including crowns or the prosthetic device attached to it; precision or semi-precision attachments; overdentures and any endodontic

Services that are covered for you	What you must pay
Dental limitations and exclusions	
treatment associated with overdentures; other customized attachments.	
<ol style="list-style-type: none"> 8. Any service related to: <ol style="list-style-type: none"> a. Altering vertical dimension of teeth b. Restoration or maintenance of occlusion c. Splinting teeth, including multiple abutments, or any service to stabilize periodontally weakened teeth d. Replacing tooth structures lost as a result of abrasion, attrition, erosion, or abfraction e. Bite registration or bite analysis 9. Infection control, including but not limited to sterilization techniques. 10. Fees for treatment performed by someone other than a dentist except for scaling and teeth cleaning, and the topical application of fluoride that can be performed by a licensed dental hygienist. The treatment must be rendered under the supervision and guidance of the dentist in accordance with generally accepted dental standards. 11. Any hospital, surgical, or treatment facility, or for services of an anesthesiologist or anesthesiologist. 12. Prescription drugs or pre-medications, whether dispensed or prescribed. 13. Any service not specifically listed in the Coverage Information. 14. Any service that we determine: Is not a dental necessity; does not offer a favorable prognosis; does not have uniform professional endorsement; or is deemed to be experimental or investigational in nature. 15. Orthodontic services. 16. Any expense incurred before your effective date or after the date your coverage under this optional supplemental benefit terminates. 17. Services provided by someone who ordinarily lives in your home or who is a family member. 18. Charges exceeding the reimbursement limit for the service. 19. Treatment resulting from any intentionally self-inflicted injury or bodily illness. 20. Local anesthetics, irrigation, nitrous oxide, bases, pulp caps, temporary dental services, study models, treatment plans, occlusal adjustments, or tissue preparation associated with the impression or placement of a restoration when charged as a separate service. These services are considered an integral part of the entire dental service. 21. Repair and replacement of orthodontic appliances. 22. Any surgical or nonsurgical treatment for any jaw joint problems, including any temporomandibular joint disorder, craniomaxillary, craniomandibular disorder, or other conditions of the joint linking the jaw bone and skull; or treatment of the facial muscles used in expression and chewing functions, for symptoms including, but not limited to, headaches. 	

Services that are covered for you	What you must pay
Dental limitations and exclusions	

23. Extractions, except for extractions of erupted tooth or exposed root (includes routine removal of tooth structure, minor smoothing of socket bone, and closure, as necessary), or surgical removal of erupted tooth requiring elevation of mucoperiosteal flap and removal of bone of section of tooth.

Excess coverage

We will not pay benefits for any accidental injury if other insurance will provide payments or expense coverage, regardless of whether the other coverage is described as primary, excess, or contingent. If your claim against another insurer is denied or partially paid, we will process your claim according to the terms and conditions of this certificate. If we make a payment, you agree to assign to us any right you have against the other insurer for dental expenses we pay. Payments made by the other insurer will be credited toward any applicable coinsurance or calendar year deductibles.

It's your responsibility to understand your dental coverage, including its limitations and exclusions. To be covered, all dental services must be received from a licensed dentist who deems the service necessary and must be approved by the plan. Remember, the greatest savings on covered services are through OSB network dentists. The dentist you choose may ask you to sign an informed consent document detailing the risks, covered dental services, and options to all recommended treatments. You should always ask the dentist for a treatment plan detailing the services to be performed and the associated costs prior to having work performed.

Coverage information

Vision benefit through EyeMed

- The MyOption Plus optional supplemental benefit includes coverage for a routine eye exam for members who wear eyeglasses, standard lenses, and eyeglass frames as follows:

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Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you	What you must pay	
Covered vision benefits	EyeMed Network Vision Provider	Non-EyeMed Network Vision Provider
<ul style="list-style-type: none"> Routine exam for members who wear eyeglasses with refraction/dilation as necessary 	\$40 allowance*	\$40 allowance
*Visit any in-network EyeMed Select vision provider and your routine exam charge will not exceed the \$40 allowance.		
<ul style="list-style-type: none"> One set of eyeglass frames and one pair of lenses (eyeglass lens treatments to include polycarbonate, UV, scratch resistance and transitional tinting) Contact lenses (instead of frames; includes conventional or disposable) 	\$290 benefit	\$290 (combined in and out-of-network)
Frequency		
<ul style="list-style-type: none"> Routine examination – Once every 12 months One set of eyeglass frames and one pair of lenses or contact lenses – Once every 12 months 		

Services that are covered for you

What you must pay

Choosing a vision provider

You may choose to get vision care from either an EyeMed vision provider or a non-EyeMed vision provider. Choosing an EyeMed vision provider from the OSB Provider Directory will decrease your costs for vision OSB services.

- To find a provider for your optional supplemental benefits, see your OSB Provider Directory. It will be sent to you within 10 days of enrolling in an OSB.
- If you do not receive an OSB Provider Directory or need help finding an EyeMed provider, please call EyeMed at the phone number at the end of this document. To get the in-network rate, make sure your provider is in the EyeMed Select network before you get care. We are not responsible for the availability or ongoing participation of any provider.

After you have chosen an EyeMed vision provider, just call the provider's office and make an appointment. Be sure to tell the provider's office that you are a Humana Medicare Advantage member with EyeMed benefits. If you have questions about EyeMed vision providers in your area or any other questions about your vision coverage under MyOption Plus, please call EyeMed at the phone number at the end of this document.

If you choose to get vision care from a non-EyeMed vision provider, you will have to pay the full bill at the time of your appointment. Then you will submit an EyeMed out-of-network claim. You must include an itemized statement of charges to EyeMed Vision Care. The out-of-network claim form can be found on MyHumana by clicking on Vision Information.

Whether you choose an EyeMed vision provider or a non-EyeMed vision provider, you must pay for any copayment and any costs and fees that exceed your covered vision benefit allowance, and any services or materials that are not covered under MyOption Plus.

How to submit a paper claim

If you receive emergency services or other services from a non-network provider, you will have to pay the full cost of those services and then submit claims documentation for payment consideration. Within 90 days, call EyeMed Customer Service at the phone number at the end of this document to request a claims form and instructions on submitting your claim. The out-of-network claim form can also be found on MyHumana by clicking on Vision Information.

General provisions

EyeMed is an independent provider. Humana's obligations are limited to payment for services described in this document.

Services that are covered for you	What you must pay
Vision limitations and exclusions	
The MyOption Plus optional supplemental benefit does not include coverage for the following:	
<ol style="list-style-type: none"> 1. Standard contact lens fit and follow-up. 2. Refitting or change in lens design after initial fitting. 3. No more than one set of eyeglass frames and one pair of lenses per calendar year. 4. The benefit dollars can only be used one time. Any remaining benefit dollars do not "roll over" to a future purchase. 5. Any expense arising from the completion of forms. 6. Any service not specifically listed in your optional supplemental benefit. 7. Orthoptic or vision training. 8. Subnormal vision aids and associated testing. 9. Aniseikonic lenses. 10. Any service we consider cosmetic. 11. Any expense incurred before your effective date or after the date your coverage under this optional supplemental benefit terminates. 12. Services provided by someone who ordinarily lives in your home or who is a family member. 13. Charges exceeding the allowance for the service. 14. Treatment resulting from any intentionally self-inflicted injury or bodily illness. 15. Plano lenses. 16. Medical or surgical treatment of eye, eyes, or supporting structures. 17. Non-prescription sunglasses. 18. Two pair of glasses in lieu of bifocals. 19. Services or materials provided by any other group benefit plans providing vision care. 20. Certain name brands when manufacturer imposes no discount. 21. Corrective vision treatment of an experimental nature. 22. Solutions and/or cleaning products for glasses or contact lenses. 23. Non-prescription items. 24. Costs associated with securing materials. 25. Pre- and post-operative services. 26. Orthokeratology. 27. Routine maintenance of materials. 28. Artistically painted lenses. 29. Any expenses incurred while you qualify for any workers' compensation or occupational disease act or law, whether or not you applied for coverage. 30. Services that are: <ol style="list-style-type: none"> a. Free or that you would not be required to pay for if you did not have this insurance, unless charges are received from and reimbursable to the U.S. government or any of its agencies as required by law; 	

Services that are covered for you	What you must pay
Vision limitations and exclusions	
<ul style="list-style-type: none"> b. Furnished by, or payable under, any plan or law through any government or any political subdivision (this does not include Medicare or Medicaid); or c. Furnished by any U.S. government-owned or operated hospital/institution/agency for any service connected with sickness or bodily injury. <ul style="list-style-type: none"> 31. Any loss caused or contributed by: war or any act of war, whether declared or not; any act of international armed conflict; or any conflict involving armed forces of any international authority. 32. Your failure to keep an appointment. 33. Any hospital, surgical or treatment facility, or for services of an anesthesiologist or anesthesiologist. 34. Prescription drugs or pre-medications, whether dispensed or prescribed. 35. Any service that we determine is not a visual necessity; does not offer a favorable prognosis; does not have uniform professional endorsement; or is deemed to be experimental or investigational in nature. 36. Replacement of lenses or eyeglass frames furnished under this optional supplemental benefit which are lost or broken, unless otherwise available under the optional supplemental benefit. 37. Any examination or material required by an employer as a condition of employment or safety eyewear. 38. Pathological treatment. 	

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)

Services that are covered for you	What you must pay
Questions?	
<p>To request an optional supplemental benefit application, call Humana Customer Care at 1-800-457-4708 For TTY, call 711 Seven days a week, 8 a.m. – 8 p.m. local time</p> <p>Please note that our automated phone system may answer during weekends and holidays from February 15 – September 30. Please leave your name and telephone number, and we will call you back by the end of the next business day.</p> <p>For information on DENTAL benefits, call HumanaDental Customer Care at 1-800-669-6614 For TTY, call 711 Monday – Friday, 8 a.m. – 6 p.m. local time</p> <p>For information on VISION benefits, call EyeMed Customer Service at 1-888-289-0595 For TTY, call 711 Monday – Saturday, 7:30 a.m. – 11 p.m. Eastern time Sunday, 11 a.m. – 8 p.m. Eastern time</p> <p>Visit Humana.com</p>	

SECTION 3 What benefits are not covered by the plan?

Section 3.1 Benefits we do not cover (exclusions)

This section tells you what kinds of benefits are "excluded." Excluded means that the plan doesn't cover these benefits.

The list below describes some services and items that aren't covered under any conditions and some that are excluded only under specific conditions.

If you get benefits that are excluded, you must pay for them yourself. We won't pay for the excluded medical benefits listed in this section (or elsewhere in this booklet), and neither will Original Medicare. The only exception: If a benefit on the exclusion list is found upon appeal to be a medical benefit that we should have paid for or covered because of your specific situation. (For information about appealing a decision we have made to not cover a medical service, go to Chapter 9, Section 5.3 in this booklet.)

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)
Chapter 4: Medical Benefits Chart (what is covered and what you pay)

In addition to any exclusions or limitations described in the Benefits Chart, or anywhere else in this Evidence of Coverage, **the following items and services aren't covered under Original Medicare or by our plan:**

- Services considered not reasonable and necessary, according to the standards of Original Medicare, unless these services are listed by our plan as covered services.
- Experimental medical and surgical procedures, equipment and medications, unless covered by Original Medicare or under a Medicare-approved clinical research study or by our plan. (See Chapter 3, Section 5 for more information on clinical research studies.) Experimental procedures and items are those items and procedures determined by our plan and Original Medicare to not be generally accepted by the medical community.
- Surgical treatment for morbid obesity, except when it is considered medically necessary and covered under Original Medicare.
- Private room in a hospital, except when it is considered medically necessary.
- Private duty nurses.
- Personal items in your room at a hospital or a skilled nursing facility, such as a telephone or a television.
- Full-time nursing care in your home.
- Custodial care is care provided in a nursing home, hospice, or other facility setting when you do not require skilled medical care or skilled nursing care. Custodial care is personal care that does not require the continuing attention of trained medical or paramedical personnel, such as care that helps you with activities of daily living, such as bathing or dressing.
- Homemaker services include basic household assistance, including light housekeeping or light meal preparation.
- Fees charged by your immediate relatives or members of your household.
- Meals delivered to your home.
- Elective or voluntary enhancement procedures or services (including weight loss, hair growth, sexual performance, athletic performance, cosmetic purposes, anti-aging and mental performance), except when medically necessary.
- Cosmetic surgery or procedures, unless because of an accidental injury or to improve a malformed part of the body. However, all stages of reconstruction are covered for a breast after a mastectomy, as well as for the unaffected breast to produce a symmetrical appearance.
- Routine dental care such as cleanings, fillings, or dentures. However, non-routine dental care required to treat illness or injury may be covered as inpatient or outpatient care.
- Chiropractic care, other than manual manipulation of the spine consistent with Medicare coverage guidelines.
- Routine foot care, except for the limited coverage provided according to Medicare guidelines.
- Orthopedic shoes, unless the shoes are part of a leg brace and are included in the cost of the brace or the shoes are for a person with diabetic foot disease.
- Supportive devices for the feet, except for orthopedic or therapeutic shoes for people with diabetic foot disease.
- Hearing aids and routine hearing examinations.
- Eyeglasses, routine eye examinations, radial keratotomy, LASIK surgery, vision therapy, and other low vision aids. However, eyeglasses are covered for people after cataract surgery.
- Reversal of sterilization procedures, sex change operations, and non-prescription contraceptive supplies.
- Acupuncture.
- Naturopath services (uses natural or alternative treatments).
- Services provided to veterans in Veterans Affairs (VA) facilities. However, when emergency services are received at VA hospital and the VA cost sharing is more than the cost sharing under our plan, we will reimburse veterans for the difference. Members are still responsible for our cost-sharing amounts.

The plan will not cover the excluded services listed above. Even if you receive the services at an emergency facility, the excluded services are still not covered.

Chapter 5. Using the plan's coverage for your Part D prescription drugs

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**Did you know there are programs to help people pay for their drugs?**

There are programs to help people with limited resources pay for their drugs. The "Extra Help" program helps people with limited resources pay for their drugs. For more information, see Chapter 2, Section 7.

Are you currently getting help to pay for your drugs?

If you are in a program that helps pay for your drugs, **some information in this Evidence of Coverage about the costs for Part D prescription drugs may not apply to you.** We send you a separate mailing containing the "Evidence of Coverage Rider for People Who Get Extra Help Paying for Prescription Drugs" (also known as the "Low Income Subsidy Rider" or the "LIS Rider"), which tells you about your drug coverage. If you do not have this mailing, please call Customer Care and ask for the "LIS Rider." (Phone numbers for Customer Care are printed on the back cover of this booklet.)

SECTION 1 Introduction

Section 1.1 This chapter describes your coverage for Part D drugs

This chapter explains rules for using your coverage for Part D drugs. The next chapter tells what you pay for Part D drugs (Chapter 6, What you pay for your Part D prescription drugs).

In addition to your coverage for Part D drugs, Humana Gold Plus H0108-004 (HMO) also covers some drugs under the plan's medical benefits:

- The plan covers drugs you are given during covered stays in the hospital or in a skilled nursing facility. Chapter 4 (Medical Benefits Chart, what is covered and what you pay) tells about the benefits and costs for drugs during a covered hospital or skilled nursing facility stay.
- Medicare Part B also provides benefits for some drugs. Part B drugs include certain chemotherapy drugs, certain drug injections you are given during an office visit, and drugs you are given at a dialysis facility. Chapter 4 (Medical Benefits Chart, what is covered and what you pay) tells about your benefits and costs for Part B drugs.

The two examples of drugs described above are covered by the plan's medical benefits. The rest of your prescription drugs are covered under the plan's Part D benefits.

Section 1.2 Basic rules for the plan's Part D drug coverage

The plan will generally cover your drugs as long as you follow these basic rules:

- You must have a provider (a doctor or other prescriber) write your prescription.
- You must use a network pharmacy to fill your prescription. (See Section 2, Fill your prescriptions at a network pharmacy or through the plan's mail-order service.)
- Your drug must be in the plan's Prescription Drug Guide (Formulary) (we call it the "Drug Guide" for short). (See Section 3, Your drugs need to be in the plan's Drug Guide.)
- Your drug must be used for a medically accepted indication. A "medically accepted indication" is a use of the drug that is either approved by the Food and Drug Administration or supported by certain reference books. (See Section 3 for more information about a medically accepted indication.)

SECTION 2 Fill your prescription at a network pharmacy or through the plan's mail-order service

Section 2.1 To have your prescription covered, use a network pharmacy

In most cases, your prescriptions are covered only if they are filled at the plan's network pharmacies. (See Section 2.5 for information about when we would cover prescriptions filled at out-of-network pharmacies.)

A network pharmacy is a pharmacy that has a contract with the plan to provide your covered prescription drugs. The term "covered drugs" means all of the Part D prescription drugs that are covered by the plan's Drug Guide.

Section 2.2 Finding network pharmacies
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How do you find a network pharmacy in your area?

To find a network pharmacy, you can look in your Provider Directory, visit our website (**Humana.com**), or call Customer Care (phone numbers are printed on the back cover of this booklet). Choose whatever is easiest for you.

You may go to any of our network pharmacies.

If you switch from one network pharmacy to another, and you need a refill of a drug you have been taking, you can ask either to have a new prescription written by a provider or have your prescription transferred to your new network pharmacy.

What if the pharmacy you have been using leaves the network?

If the pharmacy you have been using leaves the plan's network, you will have to find a new pharmacy that is in the network. To find another network pharmacy in your area, you can get help from Customer Care (phone numbers are printed on the back cover of this booklet) or use the Provider Directory. You can also find information on our website at **Humana.com**.

What if you need a specialized pharmacy?

Sometimes prescriptions must be filled at a specialized pharmacy. Specialized pharmacies include:

- Pharmacies that supply drugs for home infusion therapy.
- Pharmacies that supply drugs for residents of a long-term care facility. Usually, a long-term care facility (such as a nursing home) has its own pharmacy. Residents may get prescription drugs through the facility's pharmacy as long as it is part of our network. If your long-term care pharmacy is not in our network, please contact Customer Care.
- Pharmacies that serve the Indian Health Service / Tribal / Urban Indian Health Program (not available in Puerto Rico). Except in emergencies, only Native Americans or Alaska Natives have access to these pharmacies in our network.
- Pharmacies that dispense drugs that are restricted by the FDA to certain locations or that require special handling, provider coordination, or education on their use. (Note: This scenario should happen rarely.)

To locate a specialized pharmacy, look in your Provider Directory or call Customer Care (phone numbers are printed on the back cover of this booklet).

Section 2.3 Using the plan's mail-order services

For certain kinds of drugs, you can use the plan's network mail-order services. Generally, the drugs available through mail order are drugs that you take on a regular basis, for a chronic or long-term medical condition. The drugs available through our plan's mail-order service are marked as **"mail-order" drugs** in our Drug Guide.

Our plan's mail-order service allows you to order **up to a 90-day supply**.

Preferred mail-order pharmacies are mail-order pharmacies in our network where the plan has negotiated lower cost sharing for members for covered drugs than at non-preferred mail-order pharmacies. However, you will usually have access to lower drug prices at non-preferred mail-order pharmacies than at out-of-network pharmacies. You may go to either of these types of network mail-order pharmacies to receive your covered prescription drugs.

To get order forms and information about filling your prescriptions by mail, please contact Customer Care.

Usually a mail-order pharmacy order will get to you in no more than 14 days. **We recommend that you discuss with your physician the option of writing a prescription for a 30-day supply to fill at a network retail pharmacy along with your prescription for mail-order, in case your order is delayed.**

Section 2.4 How can you get a long-term supply of drugs?

When you get a long-term supply of drugs, your cost sharing may be lower. The plan offers two ways to get a long-term supply of "maintenance" drugs in our plan's Drug Guide. (Maintenance drugs are drugs that you take on a regular basis, for a chronic or long-term medical condition.)

1. **Some retail pharmacies** in our network allow you to get a long-term supply of maintenance drugs. Some of these retail pharmacies may agree to accept the mail-order cost-sharing amount for a long-term supply of maintenance drugs. Other retail pharmacies may not agree to accept the mail-order cost-sharing amounts for a long-term supply of maintenance drugs. In this case you will be responsible for the difference in price. Your Provider Directory tells you which pharmacies in our network can give you a long-term supply of maintenance drugs. You can also call Customer Care for more information (phone numbers are printed on the back cover of this booklet).
2. For certain kinds of drugs, you can use the plan's network **mail-order services**. The drugs available through our plan's mail-order service are marked as **"mail-order" drugs** in our plan's Drug Guide. Our plan's mail-order service requires you to order at least a 30-day supply of the drug and no more than a 90-day supply. See Section 2.3 for more information about using our mail-order services.

Section 2.5 When can you use a pharmacy that is not in the plan's network?

Your prescription may be covered in certain situations

We have network pharmacies outside of our service area where you can get your prescriptions filled as a member of our plan. Generally, we cover drugs filled at an out-of-network pharmacy only when you are not able to use a network pharmacy. Here are the circumstances when we would cover prescriptions filled at an out-of-network pharmacy:

- **If you need a prescription because of a medical emergency**
 - We will cover prescriptions that are filled at an out-of-network pharmacy if the prescriptions are related to care for a medical emergency or urgently needed care. In this situation, you will have to pay the full cost

(rather than paying just your copayment or coinsurance) when you fill your prescription. You can ask us to reimburse you for our share of the cost by submitting a paper claim form. If you go to an out-of-network pharmacy, you may be responsible for paying the difference between what we would pay for a prescription filled at an in-network pharmacy and what the out-of-network pharmacy charged for your prescription. (Chapter 7, Section 2.1 explains how to ask the plan to pay you back.)

- **If you need coverage while you are traveling away from the plan's service area**
 - If you take a prescription drug on a regular basis and you are going on a trip, be sure to check your supply of the drug before you leave. When possible, take along all the medication you will need. You may be able to order your prescription drugs ahead of time through our preferred prescription home delivery service (mail-order) or through a retail network pharmacy that offers an extended supply. If you are traveling outside of your plan's service area but within the United States and territories and become ill, or run out of your prescription drugs, call Customer Care to find a network pharmacy in your area where you can fill your prescription. If a network pharmacy is not available, we will cover prescriptions that are filled at an out-of-network pharmacy if you follow all other coverage rules identified within this document. In this situation, you will have to pay the full cost (rather than paying just your copayment or coinsurance) when you fill your prescription.
 - You may be responsible for paying the difference between what we would pay for a prescription filled at an in-network pharmacy and what the out-of-network pharmacy charged for your prescription. You can ask us to reimburse you for our share of the cost by submitting a paper claim form. (Chapter 7, Section 2.1 explains how to ask the plan to pay you back.)
 - **Please recognize, however, that multiple non-emergency occurrences of out-of-network pharmacy claims will result in claim denials. In addition, we cannot pay for any stolen medications or prescriptions that are filled by pharmacies outside the United States and territories, even for a medical emergency.**

Other times you can get your prescription covered if you go to an out-of-network pharmacy.

We will cover your prescription at an out-of-network pharmacy if at least one of the following applies:

- If you are unable to get a covered drug in a timely manner because there is no network pharmacy within a reasonable driving distance providing 24-hour service.
- If you are trying to fill a covered prescription drug that is not regularly stocked at a network retail or mail-order pharmacy (these drugs include orphan drugs or other specialty pharmaceuticals).
- If you get a covered prescription drug from an institutional based pharmacy while a patient in an emergency room, provider based clinic, outpatient surgery clinic, or other outpatient setting.
- If you are automatically enrolled in our plan because you are Medicaid eligible and have a seven-month retroactive enrollment period.
- If you become evacuated due to a state or federal emergency disaster declaration or other public health emergency declaration and cannot readily find an in-network pharmacy.

In these situations, **please check first with Customer Care** to see if there is a network pharmacy nearby. (Phone numbers for Customer Care are printed on the back cover of this booklet.)

How do you ask for reimbursement from the plan?

If you must use an out-of-network pharmacy, you will generally have to pay the full cost (rather than your normal share of the cost) when you fill your prescription. You can ask us to reimburse you for our share of the cost. (Chapter 7, Section 2.1 explains how to ask the plan to pay you back.)

SECTION 3 Your drugs need to be in the plan's "Drug Guide"

Section 3.1 The "Drug Guide" tells which Part D drugs are covered

The plan has a "Prescription Drug Guide (Formulary)." In this Evidence of Coverage, **we call it the "Drug Guide" for short.**

The drugs on this list are selected by the plan with the help of a team of doctors and pharmacists. The list must meet requirements set by Medicare. Medicare has approved the plan's Drug Guide.

The drugs in the Drug Guide are only those covered under Medicare Part D (earlier in this chapter, Section 1.1 explains about Part D drugs).

We will generally cover a drug in the plan's Drug Guide as long as you follow the other coverage rules explained in this chapter and the use of the drug is a medically accepted indication. A "medically accepted indication" is a use of the drug that is either:

- approved by the Food and Drug Administration. (That is, the Food and Drug Administration has approved the drug for the diagnosis or condition for which it is being prescribed.)
- -- or -- supported by certain reference books. (These reference books are the American Hospital Formulary Service Drug Information, the DRUGDEX Information System, and the USPDI or its successor.)

The Drug Guide includes both brand-name and generic drugs

A generic drug is a prescription drug that has the same active ingredients as the brand-name drug. Generally, it works just as well as the brand-name drug and usually costs less. There are generic drug substitutes available for many brand-name drugs.

Our plan also covers certain over-the-counter drugs. Some over-the-counter drugs are less expensive than prescription drugs and work just as well. For more information, call Customer Care (phone numbers are printed on the back cover of this booklet).

What is not in the Drug Guide?

The plan does not cover all prescription drugs.

- In some cases, the law does not allow any Medicare plan to cover certain types of drugs (for more information about this, see Section 7.1 in this chapter).
- In other cases, we have decided not to include a particular drug in the Drug Guide.

Section 3.2 There are five "cost-sharing tiers" for drugs in the Drug Guide

Every drug in the plan's Drug Guide is in one of five cost-sharing tiers. In general, the higher the cost-sharing tier, the higher your cost for the drug:

- **Cost-Sharing Tier 1 – Preferred Generic:** Generic or brand drugs that are available at the lowest cost share for this plan.
- **Cost-Sharing Tier 2 – Non-Preferred Generic:** Generic or brand drugs that Humana offers at a higher cost to you than Tier 1 Preferred Generic drugs.
- **Cost-Sharing Tier 3 – Preferred Brand:** Generic or brand drugs that Humana offers at a lower cost to you than Tier 4 Non-Preferred Brand drugs.

- **Cost-Sharing Tier 4 – Non-Preferred Brand:** Generic or brand drugs that Humana offers at a higher cost to you than Tier 3 Preferred Brand drugs.
- **Cost-Sharing Tier 5 – Specialty:** Some injectables and other high-cost drugs.

To find out which cost-sharing tier your drug is in, look it up in the plan's Drug Guide.

The amount you pay for drugs in each cost-sharing tier is shown in Chapter 6 (What you pay for your Part D prescription drugs).

Section 3.3 How can you find out if a specific drug is in the Drug Guide?

You have three ways to find out:

1. Check the most recent Drug Guide we sent you in the mail. Please note: The Drug Guide we send includes information for the covered drugs that are most commonly used by our members. However, we cover additional drugs that are not included in the printed Drug Guide. If one of your drugs is not listed in the Drug Guide, you should visit our website or contact Customer Care to find out if we cover it.
2. Visit the plan's website (**Humana.com**). The Drug Guide on the website is always the most current.
3. Call Customer Care to find out if a particular drug is in the plan's Drug Guide or to ask for a copy of the list. (Phone numbers for Customer Care are printed on the back cover of this booklet.)

SECTION 4 There are restrictions on coverage for some drugs

Section 4.1 Why do some drugs have restrictions?

For certain prescription drugs, special rules restrict how and when the plan covers them. A team of doctors and pharmacists developed these rules to help our members use drugs in the most effective ways. These special rules also help control overall drug costs, which keeps your drug coverage more affordable.

In general, our rules encourage you to get a drug that works for your medical condition and is safe and effective. Whenever a safe, lower-cost drug will work just as well medically as a higher-cost drug, the plan's rules are designed to encourage you and your provider to use that lower-cost option. We also need to comply with Medicare's rules and regulations for drug coverage and cost sharing.

If there is a restriction for your drug, it usually means that you or your provider will have to take extra steps in order for us to cover the drug. If you want us to waive the restriction for you, you will need to use the coverage decision process and ask us to make an exception. We may or may not agree to waive the restriction for you. (See Chapter 9, Section 6.2 for information about asking for exceptions.)

Section 4.2 What kinds of restrictions?

Our plan uses different types of restrictions to help our members use drugs in the most effective ways. The sections below tell you more about the types of restrictions we use for certain drugs.

Restricting brand-name drugs when a generic version is available

Generally, a "generic" drug works the same as a brand-name drug and usually costs less. **When a generic version of a brand-name drug is available, our network pharmacies will provide you the generic version.** We usually will not cover the brand-name drug when a generic version is available. However, if your provider has told us the

medical reason that neither the generic drug nor other covered drugs that treat the same condition will work for you, then we will cover the brand-name drug. (Your share of the cost may be greater for the brand-name drug than for the generic drug.)

Getting plan approval in advance

For certain drugs, you or your provider need to get approval from the plan before we will agree to cover the drug for you. This is called "**prior authorization**." Sometimes the requirement for getting approval in advance helps guide appropriate use of certain drugs. If you do not get this approval, your drug might not be covered by the plan.

Trying a different drug first

This requirement encourages you to try less costly but just as effective drugs before the plan covers another drug. For example, if Drug A and Drug B treat the same medical condition, the plan may require you to try Drug A first. If Drug A does not work for you, the plan will then cover Drug B. This requirement to try a different drug first is called "**step therapy**."

Quantity limits

For certain drugs, we limit the amount of the drug that you can have. For example, the plan might limit how many refills you can get, or how much of a drug you can get each time you fill your prescription. For example, if it is normally considered safe to take only one pill per day for a certain drug, we may limit coverage for your prescription to no more than one pill per day.

Section 4.3 Do any of these restrictions apply to your drugs?

The plan's Drug Guide includes information about the restrictions described above. To find out if any of these restrictions apply to a drug you take or want to take, check the Drug Guide. For the most up-to-date information, call Customer Care (phone numbers are printed on the back cover of this booklet) or check our website **Humana.com**.

If there is a restriction for your drug, it usually means that you or your provider will have to take extra steps in order for us to cover the drug. If there is a restriction on the drug you want to take, you should contact Customer Care to learn what you or your provider would need to do to get coverage for the drug. If you want us to waive the restriction for you, you will need to use the coverage decision process and ask us to make an exception. We may or may not agree to waive the restriction for you. (See Chapter 9, Section 6.2 for information about asking for exceptions.)

SECTION 5 What if one of your drugs is not covered in the way you'd like it to be covered?

Section 5.1 There are things you can do if your drug is not covered in the way you'd like it to be covered

Suppose there is a prescription drug you are currently taking, or one that you and your provider think you should be taking. We hope that your drug coverage will work well for you, but it's possible that you might have a problem. For example:

- **What if the drug you want to take is not covered by the plan?** For example, the drug might not be covered at all. Or maybe a generic version of the drug is covered but the brand-name version you want to take is not covered.

- **What if the drug is covered, but there are extra rules or restrictions on coverage for that drug?** As explained in Section 4, some of the drugs covered by the plan have extra rules to restrict their use. For example, you might be required to try a different drug first, to see if it will work, before the drug you want to take will be covered for you. Or there might be limits on what amount of the drug (number of pills, etc.) is covered during a particular time period. In some cases, you may want us to waive the restriction for you. For example, you might want us to cover a certain drug for you without having to try other drugs first. Or you may want us to cover more of a drug (number of pills, etc.) than we normally will cover.
- **What if the drug is covered, but it is in a cost-sharing tier that makes your cost sharing more expensive than you think it should be?** The plan puts each covered drug into one of five different cost-sharing tiers. How much you pay for your prescription depends in part on which cost-sharing tier your drug is in.

There are things you can do if your drug is not covered in the way that you'd like it to be covered. Your options depend on what type of problem you have:

- If your drug is not in the Drug Guide or if your drug is restricted, go to Section 5.2 to learn what you can do.
- If your drug is in a cost-sharing tier that makes your cost more expensive than you think it should be, go to Section 5.3 to learn what you can do.

Section 5.2 What can you do if your drug is not in the Drug Guide or if the drug is restricted in some way?

If your drug is not in the Drug Guide or is restricted, here are things you can do:

- You may be able to get a temporary supply of the drug (only members in certain situations can get a temporary supply). This will give you and your provider time to change to another drug or to file a request to have the drug covered.
- You can change to another drug.
- You can request an exception and ask the plan to cover the drug or remove restrictions from the drug.

You may be able to get a temporary supply

Under certain circumstances, the plan can offer a temporary supply of a drug to you when your drug is not in the Drug Guide or when it is restricted in some way. Doing this gives you time to talk with your provider about the change in coverage and figure out what to do.

To be eligible for a temporary supply, you must meet the two requirements below:

1. The change to your drug coverage must be one of the following types of changes:

- The drug you have been taking is **no longer in the plan's Drug Guide**.
- -- or -- the drug you have been taking is **now restricted in some way** (Section 4 in this chapter tells about restrictions).

2. You must be in one of the situations described below:

- **For those members who were in the plan last year and aren't in a long-term care facility:**
We will cover a temporary supply of your drug **one time only during the first 90 days of the calendar year**. This temporary supply will be for a maximum of 30 days, or less if your prescription is written for fewer days. The prescription must be filled at a network pharmacy.
- **For those members who are new to the plan and aren't in a long-term care facility:**
We will cover a temporary supply of your drug **one time only during the first 90 days of your membership** in the plan. This temporary supply will be for a maximum of 30 days, or less if your prescription is written for fewer days. The prescription must be filled at a network pharmacy.
- **For those members who are new to the plan and reside in a long-term care facility:**

We will cover a temporary supply of your drug **during the first 90 days of your membership** in the plan. The first supply will be for a maximum of 93 days, or less if your prescription is written for fewer days. (Please note that the long-term care pharmacy may provide the drug in smaller amounts at a time to prevent waste.) If needed, we will cover additional refills during your first 90 days in the plan.

- **For those members who have been in the plan for more than 90 days and reside in a long-term care facility and need a supply right away:**

We will cover one 31-day supply, or less if your prescription is written for fewer days. This is in addition to the above long-term care transition supply.

- **Transition Supply for Current Members with changes in treatment setting:**

Throughout the plan year, you may have a change in your treatment setting due to the level of care you require. Such transitions include:

- Members who are discharged from a hospital or skilled nursing facility to a home setting
- Members who are admitted to a hospital or skilled nursing facility from a home setting
- Members who transfer from one skilled nursing facility to another and are served by a different pharmacy
- Members who end their skilled nursing facility Medicare Part A stay (where payments include all pharmacy charges) and who need to now use their Part D plan benefit
- Members who give up hospice status and revert back to standard Medicare Part A and B coverage
- Members discharged from chronic psychiatric hospitals with highly individualized drug regimens

For these changes in treatment settings, we will cover up to a 31-day supply of a Part D covered drug when your prescription is filled at a pharmacy. If you change treatment settings multiple times within the same month, you may have to request an exception or prior authorization and receive approval for continued coverage of your drug. We will review these requests for continuation of therapy on a case-by-case basis when you are stabilized on a drug regimen which, if altered, is known to have risks.

Transition policy

We want to be sure that you, as a new or existing member, safely transition into the 2014 plan year. In 2014, you may not be able to receive your current drug therapy if the drug:

- Is not in our Drug Guide
or
- Requires prior authorization because of quantity limits, step therapy requirements, or confirmation of your clinical history

Cost sharing for Drugs Provided through the Transition Policy

If you're eligible for the low-income subsidy (LIS) in 2014, your copayment or coinsurance for a temporary supply of drugs provided during your transition period won't exceed your LIS limit. If you don't receive LIS, your copayment or coinsurance will be based on your plan's approved drug cost-sharing tiers.

One-Time Transition Supply at a Retail or Mail-Order Pharmacy

Beginning Jan. 1, 2014, when you have limited ability to receive your current prescription therapy:

- We will cover a one-time, 30-day supply of a Part D-covered drug unless the prescription is written for less than 30 days during the first 90 days of your eligibility.
- After you have your 30-day supply, you'll receive a letter that explains the temporary nature of the transition medication supply. After you receive the letter, talk to your provider and decide if you should switch to an alternative drug or request an exception or prior authorization. We may not pay for refills of temporary supply drugs until an exception or prior authorization has been requested and approved.

Transition Supply for Residents of Long-Term Care Facilities

We assist members in long-term care facilities who transition between plans, have both Medicare and full Medicaid benefits, or submit an exception or an appeal request. For long-term care residents, we will cover up to a

31-day supply and two additional refills of a Part D-covered drug. This coverage is offered anytime during the first 90 days of your eligibility when your current prescription therapy is filled at a long-term care pharmacy. If your ability to receive your drug therapy is limited – but you're past the first 90 days of membership in your plan – we will cover up to a 31-day emergency supply of a Part D-covered drug so you can continue therapy while you pursue an exception or prior authorization.

Transition Extension

We make arrangements to continue to provide necessary drugs to you via an extension of the transition period, on a case-by case basis, when your exception request or appeal has not been processed by the end of your transition period.

Pharmacy and Therapeutics Committee

The Pharmacy and Therapeutics (P&T) committee has oversight of our Part D Drug Guide and associated policies. The P&T committee designed these policies for certain Part D drugs. The policies are designed to make sure the drug is used based on medically accepted clinical guidelines for indications where the drug has been proven safe and effective and is prescribed according to manufacturer recommendations.

After you receive your temporary supply of a Part D drug, your medication may require medical review if:

- It's not in the Drug Guide
or
- It requires prior authorization due to quantity limits, step therapy requirements, or confirmation of your clinical history

If you're stabilized on a drug not in the Drug Guide or a drug requiring prior authorization or have tried other drug alternatives, your provider can provide us with a statement of your clinical history to help with the prior authorization or exception request process.

Public Notice of Transition Policy

This Transition Policy is available on our website, **Humana.com**, in the same area where the Part D Formulary is displayed.

To ask for a temporary supply, call Customer Care (phone numbers are printed on the back cover of this booklet).

During the time when you are getting a temporary supply of a drug, you should talk with your provider to decide what to do when your temporary supply runs out. You can either switch to a different drug covered by the plan or ask the plan to make an exception for you and cover your current drug. The sections below tell you more about these options.

You can change to another drug

Start by talking with your provider. Perhaps there is a different drug covered by the plan that might work just as well for you. You can call Customer Care to ask for a list of covered drugs that treat the same medical condition. This list can help your provider find a covered drug that might work for you. (Phone numbers for Customer Care are printed on the back cover of this booklet.)

You can ask for an exception

You and your provider can ask the plan to make an exception for you and cover the drug in the way you would like it to be covered. If your provider says that you have medical reasons that justify asking us for an exception, your provider can help you request an exception to the rule. For example, you can ask the plan to cover a drug even though it is not in the plan's Drug Guide. Or you can ask the plan to make an exception and cover the drug without restrictions.

If you are a current member and a drug you are taking will be removed from the formulary or restricted in some way for next year, we will allow you to request a formulary exception in advance for next year. We will tell you about any change in the coverage for your drug for next year. You can ask for an exception before next year and we will give you an answer within 72 hours after we receive your request (or your prescriber's supporting statement). If we approve your request, we will authorize the coverage before the change takes effect.

If you and your provider want to ask for an exception, Chapter 9, Section 6.4 tells what to do. It explains the procedures and deadlines that have been set by Medicare to make sure your request is handled promptly and fairly.

Section 5.3 What can you do if your drug is in a cost-sharing tier you think is too high?

If your drug is in a cost-sharing tier you think is too high, here are things you can do:

You can change to another drug

If your drug is in a cost-sharing tier you think is too high, start by talking with your provider. Perhaps there is a different drug in a lower cost-sharing tier that might work just as well for you. You can call Customer Care to ask for a list of covered drugs that treat the same medical condition. This list can help your provider find a covered drug that might work for you. (Phone numbers for Customer Care are printed on the back cover of this booklet.)

You can ask for an exception

For drugs in Cost-Sharing Tier 2 – Non-Preferred Generic Drugs or Cost-Sharing Tier 4 – Non-Preferred Brand Drugs, you and your provider can ask the plan to make an exception in the cost-sharing tier for the drug so that you pay less for it. If your provider says that you have medical reasons that justify asking us for an exception, your provider can help you request an exception to the rule.

If you and your provider want to ask for an exception, Chapter 9, Section 6.4 tells what to do. It explains the procedures and deadlines that have been set by Medicare to make sure your request is handled promptly and fairly.

Drugs in some of our cost-sharing tiers are not eligible for this type of exception. We do not lower the cost-sharing amount for drugs in Cost-Sharing Tier 1 – Preferred Generic drugs, Cost-Sharing Tier 3 – Preferred Brand drugs or Cost-Sharing Tier 5 – Specialty drugs.

SECTION 6 What if your coverage changes for one of your drugs?

Section 6.1 The Drug Guide can change during the year

Most of the changes in drug coverage happen at the beginning of each year (January 1). However, during the year, the plan might make many kinds of changes to the Drug Guide. For example, the plan might:

- **Add or remove drugs from the Drug Guide.** New drugs become available, including new generic drugs. Perhaps the government has given approval to a new use for an existing drug. Sometimes, a drug gets recalled and we decide not to cover it. Or we might remove a drug from the list because it has been found to be ineffective.

- **Move a drug to a higher or lower cost-sharing tier.**
- **Add or remove a restriction on coverage for a drug** (for more information about restrictions to coverage, see Section 4 in this chapter).
- **Replace a brand-name drug with a generic drug.**

In almost all cases, we must get approval from Medicare for any changes we make to the plan's Drug Guide.

Section 6.2 What happens if coverage changes for a drug you are taking?

How will you find out if your drug's coverage has been changed?

If there is a change to coverage for a drug you are taking, the plan will send you a notice to tell you. Normally, **we will let you know at least 60 days ahead of time.**

Once in a while, a drug is **suddenly recalled** because it's been found to be unsafe or for other reasons. If this happens, the plan will immediately remove the drug from the Drug Guide. We will let you know of this change right away. Your provider will also know about this change, and can work with you to find another drug for your condition.

Do changes to your drug coverage affect you right away?

If any of the following types of changes affect a drug you are taking, the change will not affect you until January 1 of the next year if you stay in the plan:

- If we move your drug into a higher cost-sharing tier.
- If we put a new restriction on your use of the drug.
- If we remove your drug from the Drug Guide, but not because of a sudden recall or because a new generic drug has replaced it.

If any of these changes happen for a drug you are taking, then the change won't affect your use or what you pay as your share of the cost until January 1 of the next year. Until that date, you probably won't see any increase in your payments or any added restriction to your use of the drug. However, on January 1 of the next year, the changes will affect you.

In some cases, you will be affected by the coverage change before January 1:

- If a **brand-name drug you are taking is replaced by a new generic drug**, the plan must give you at least 60 days' notice or give you a 60-day refill of your brand-name drug at a network pharmacy.
 - During this 60-day period, you should be working with your provider to switch to the generic or to a different drug that we cover.
 - Or you and your provider can ask the plan to make an exception and continue to cover the brand-name drug for you. For information on how to ask for an exception, see Chapter 9 (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)).
- Again, if a drug is **suddenly recalled** because it's been found to be unsafe or for other reasons, the plan will immediately remove the drug from the Drug Guide. We will let you know of this change right away.
 - Your provider will also know about this change, and can work with you to find another drug for your condition.

SECTION 7 What types of drugs are not covered by the plan?

Section 7.1 Types of drugs we do not cover

This section tells you what kinds of prescription drugs are “excluded.” This means Medicare does not pay for these drugs.

If you get drugs that are excluded, you must pay for them yourself. We won't pay for the drugs that are listed in this section. The only exception: If the requested drug is found upon appeal to be a drug that is not excluded under Part D and we should have paid for or covered it because of your specific situation. (For information about appealing a decision we have made to not cover a drug, go to Chapter 9, Section 6.5 in this booklet.)

Here are three general rules about drugs that Medicare drug plans will not cover under Part D:

- Our plan's Part D drug coverage cannot cover a drug that would be covered under Medicare Part A or Part B.
- Our plan cannot cover a drug purchased outside the United States and its territories.
- Our plan usually cannot cover off-label use. “Off-label use” is any use of the drug other than those indicated on a drug's label as approved by the Food and Drug Administration.
 - Generally, coverage for “off-label use” is allowed only when the use is supported by certain reference books. These reference books are the American Hospital Formulary Service Drug Information, the DRUGDEX Information System, and the USPDI or its successor. If the use is not supported by any of these reference books, then our plan cannot cover its “off-label use.”

Also, by law, these categories of drugs are not covered by Medicare drug plans:

- Non-prescription drugs (also called over-the-counter drugs)
- Drugs when used to promote fertility
- Drugs when used for the relief of cough or cold symptoms
- Drugs when used for cosmetic purposes or to promote hair growth
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
- Drugs when used for the treatment of sexual or erectile dysfunction, such as Viagra, Cialis, Levitra, and Caverject
- Drugs when used for treatment of anorexia, weight loss, or weight gain
- Outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer as a condition of sale

If you receive "Extra Help" paying for your drugs, your state Medicaid program may cover some prescription drugs not normally covered in a Medicare drug plan. Please contact your state Medicaid program to determine what drug coverage may be available to you. (You can find phone numbers and contact information for Medicaid in Chapter 2, Section 6.)

SECTION 8 Show your plan membership card when you fill a prescription

Section 8.1 Show your membership card

To fill your prescription, show your plan membership card at the network pharmacy you choose. When you show your plan membership card, the network pharmacy will automatically bill the plan for our share of your covered

prescription drug cost. You will need to pay the pharmacy your share of the cost when you pick up your prescription.

Section 8.2 What if you don't have your membership card with you?

If you don't have your plan membership card with you when you fill your prescription, ask the pharmacy to call the plan to get the necessary information.

If the pharmacy is not able to get the necessary information, **you may have to pay the full cost of the prescription when you pick it up.** (You can then **ask us to reimburse you** for our share. See Chapter 7, Section 2.1 for information about how to ask the plan for reimbursement.)

SECTION 9 Part D drug coverage in special situations

Section 9.1 What if you're in a hospital or a skilled nursing facility for a stay that is covered by the plan?

If you are admitted to a hospital or to a skilled nursing facility for a stay covered by the plan, we will generally cover the cost of your prescription drugs during your stay. Once you leave the hospital or skilled nursing facility, the plan will cover your drugs as long as the drugs meet all of our rules for coverage. See the previous parts of this section that tell about the rules for getting drug coverage. Chapter 6 (What you pay for your Part D prescription drugs) gives more information about drug coverage and what you pay.

Please Note: When you enter, live in, or leave a skilled nursing facility, you are entitled to a special enrollment period. During this time period, you can switch plans or change your coverage. (Chapter 10, Ending your membership in the plan, tells when you can leave our plan and join a different Medicare plan.)

Section 9.2 What if you're a resident in a long-term care facility?

Usually, a long-term care facility (such as a nursing home) has its own pharmacy, or a pharmacy that supplies drugs for all of its residents. If you are a resident of a long-term care facility, you may get your prescription drugs through the facility's pharmacy as long as it is part of our network.

Check your Provider Directory to find out if your long-term care facility's pharmacy is part of our network. If it isn't, or if you need more information, please contact Customer Care (phone numbers are printed on the back cover of this booklet).

What if you're a resident in a long-term care facility and become a new member of the plan?

If you need a drug that is not in our Drug Guide or is restricted in some way, the plan will cover a **temporary supply** of your drug during the first 90 days of your membership. The first supply will be for a maximum of 93 days, or less if your prescription is written for fewer days. (Please note that the long-term care pharmacy may provide the drug in smaller amounts at a time to prevent waste.) If needed, we will cover additional refills during your first 90 days in the plan.

If you have been a member of the plan for more than 90 days and need a drug that is not in our Drug Guide, or if the plan has any restriction on the drug's coverage, we will cover one 31-day supply, or less if your prescription is written for fewer days.

During the time when you are getting a temporary supply of a drug, you should talk with your provider to decide what to do when your temporary supply runs out. Perhaps there is a different drug covered by the plan that might work just as well for you. Or you and your provider can ask the plan to make an exception for you and cover the drug in the way you would like it to be covered. If you and your provider want to ask for an exception, Chapter 9, Section 6.4 tells what to do.

Section 9.3 What if you're also getting drug coverage from an employer or retiree group plan?

Do you currently have other prescription drug coverage through your (or your spouse's) employer or retiree group? If so, please contact **that group's benefits administrator**. He or she can help you determine how your current prescription drug coverage will work with our plan.

In general, if you are currently employed, the prescription drug coverage you get from us will be secondary to your employer or retiree group coverage. That means your group coverage would pay first.

Special note about 'creditable coverage':

Each year your employer or retiree group should send you a notice that tells if your prescription drug coverage for the next calendar year is "creditable" and the choices you have for drug coverage.

If the coverage from the group plan is "**creditable**," it means that the plan has drug coverage that is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage.

Keep these notices about creditable coverage, because you may need them later. If you enroll in a Medicare plan that includes Part D drug coverage, you may need these notices to show that you have maintained creditable coverage. If you didn't get a notice about creditable coverage from your employer or retiree group plan, you can get a copy from the employer or retiree plan's benefits administrator or the employer or union.

SECTION 10 Programs on drug safety and managing medications

Section 10.1 Programs to help members use drugs safely

We conduct drug use reviews for our members to help make sure that they are getting safe and appropriate care. These reviews are especially important for members who have more than one provider who prescribes their drugs.

We do a review each time you fill a prescription. We also review our records on a regular basis. During these reviews, we look for potential problems such as:

- Possible medication errors.
- Drugs that may not be necessary because you are taking another drug to treat the same medical condition.
- Drugs that may not be safe or appropriate because of your age or gender.
- Certain combinations of drugs that could harm you if taken at the same time.
- Prescriptions written for drugs that have ingredients you are allergic to.

- Possible errors in the amount (dosage) of a drug you are taking.

If we see a possible problem in your use of medications, we will work with your provider to correct the problem.

Section 10.2 Programs to help members manage their medications

We have programs that can help our members with special situations. For example, some members have several complex medical conditions or they may need to take many drugs at the same time, or they could have very high drug costs.

These programs are voluntary and free to members. A team of pharmacists and doctors developed the programs for us. The programs can help make sure that our members are using the drugs that work best to treat their medical conditions and help us identify possible medication errors.

One program is called a Medication Therapy Management (MTM) program. Some members who take several medications for different medical conditions may qualify. A pharmacist or other health professional will give you a comprehensive review of all your medications. You can talk about how best to take your medications, your costs, or any problems you're having. You'll get a written summary of this discussion. The summary has a medication action plan that recommends what you can do to make the best use of your medications, with space for you to take notes or write down any follow-up questions. You'll also get a personal medication list that will include all the medications you're taking and why you take them.

If we have a program that fits your needs, we will automatically enroll you in the program and send you information. If you decide not to participate, please notify us and we will withdraw you from the program. If you have any questions about these programs, please contact Customer Care (phone numbers are printed on the back cover of this booklet).

Chapter 6. What you pay for your Part D prescription drugs

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**Did you know there are programs to help people pay for their drugs?**

The "Extra Help" program helps people with limited resources pay for their drugs. For more information, see Chapter 2, Section 7.

Are you currently getting help to pay for your drugs?

If you are in a program that helps pay for your drugs, **some information in this Evidence of Coverage about the costs for Part D prescription drugs may not apply to you.** We send you a separate mailing containing the "Evidence of Coverage Rider for People Who Get Extra Help Paying for Prescription Drugs" (also known as the "Low Income Subsidy Rider" or the "LIS Rider"), which tells you about your drug coverage. If you don't have this mailing, please call Customer Care and ask for the "LIS Rider." (Phone numbers for Customer Care are printed on the back cover of this booklet.)

SECTION 1 Introduction

Section 1.1 Use this chapter together with other materials that explain your drug coverage

This chapter focuses on what you pay for your Part D prescription drugs. To keep things simple, we use "drug" in this chapter to mean a Part D prescription drug. As explained in Chapter 5, not all drugs are Part D drugs – some drugs are covered under Medicare Part A or Part B and other drugs are excluded from Medicare coverage by law.

To understand the payment information we give you in this chapter, you need to know the basics of what drugs are covered, where to fill your prescriptions, and what rules to follow when you get your covered drugs. Here are materials that explain these basics:

- **The plan's Prescription Drug Guide (Formulary).** To keep things simple, we call this the "Drug Guide."
 - This Drug Guide tells which drugs are covered for you.
 - It also tells which of the five "cost-sharing tiers" the drug is in and whether there are any restrictions on your coverage for the drug.
 - If you need a copy of the Drug Guide, call Customer Care (phone numbers are printed on the back cover of this booklet). You can also find the Drug Guide on our website at **Humana.com**. The Drug Guide on the website is always the most current.
- **Chapter 5 of this booklet.** Chapter 5 gives the details about your prescription drug coverage, including rules you need to follow when you get your covered drugs. Chapter 5 also tells which types of prescription drugs are not covered by our plan.
- **The plan's Provider Directory.** In most situations you must use a network pharmacy to get your covered drugs (see Chapter 5 for the details). The Provider Directory has a list of pharmacies in the plan's network. It also tells you which pharmacies in our network can give you a long-term supply of a drug (such as filling a prescription for a three-month's supply).

Section 1.2 Types of out-of-pocket costs you may pay for covered drugs

To understand the payment information we give you in this chapter, you need to know about the types of out-of-pocket costs you may pay for your covered services. The amount that you pay for a drug is called "cost-sharing," and there are three ways you may be asked to pay.

- The **"deductible"** is the amount you must pay for drugs before our plan begins to pay its share.

- **"Copayment"** means that you pay a fixed amount each time you fill a prescription.
- **"Coinsurance"** means that you pay a percent of the total cost of the drug each time you fill a prescription.

SECTION 2 What you pay for a drug depends on which "drug payment stage" you are in when you get the drug

Section 2.1 What are the drug payment stages for Humana Gold Plus H0108-004 (HMO) members?

As shown in the table below, there are "drug payment stages" for your prescription drug coverage under Humana Gold Plus H0108-004 (HMO). How much you pay for a drug depends on which of these stages you are in at the time you get a prescription filled or refilled.

Stage 1 <u>Yearly Deductible Stage</u>	Stage 2 <u>Initial Coverage Stage</u>	Stage 3 <u>Coverage Gap Stage</u>	Stage 4 <u>Catastrophic Coverage Stage</u>
<p>Because there is no deductible for the plan, this payment stage does not apply to you.</p>	<p>You begin in this stage when you fill your first prescription of the year.</p> <p>During this stage, the plan pays its share of the cost of your drugs and you pay your share of the cost.</p> <p>You stay in this stage until your year-to-date "total drug costs" (your payments plus any Part D plan's payments) total \$2,850</p> <p>(Details are in Section 5 of this chapter.)</p>	<p>During this stage, the plan provides coverage for the following:</p> <ul style="list-style-type: none"> • Select Home Infusion Drugs <p>For all other drugs, you pay 47.5% of the price for brand-name drugs (plus a portion of the dispensing fee) and will generally pay no more than 72% of the price for generic drugs.</p> <p>You stay in this stage until your year-to-date "out-of-pocket costs" (your payments) reach a total of \$4,550. This amount and rules for counting costs toward this amount have been set by Medicare.</p> <p>(Details are in Section 6 of this chapter.)</p>	<p>During this stage, the plan will pay most of the cost of your drugs for the rest of the calendar year (through December 31, 2014).</p> <p>(Details are in Section 7 of this chapter.)</p>

SECTION 3 We send you reports that explain payments for your drugs and which payment stage you are in

Section 3.1 We send you a monthly report called the "SmartSummary"

Our plan keeps track of the costs of your prescription drugs and the payments you have made when you get your prescriptions filled or refilled at the pharmacy. This way, we can tell you when you have moved from one drug payment stage to the next. In particular, there are two types of costs we keep track of:

- We keep track of how much you have paid. This is called your **"out-of-pocket"** cost.
- We keep track of your **"total drug costs."** This is the amount you pay out-of-pocket or others pay on your behalf plus the amount paid by the plan.

Our plan will prepare a written report called the SmartSummary when you have had one or more prescriptions filled through the plan during the previous month. It includes:

- **Information for that month.** This report gives the payment details about the prescriptions you have filled during the previous month. It shows the total drug costs, what the plan paid, and what you and others on your behalf paid.
- **Totals for the year since January 1.** This is called "year-to-date" information. It shows you the total drug costs and total payments for your drugs since the year began.

Section 3.2 Help us keep our information about your drug payments up to date

To keep track of your drug costs and the payments you make for drugs, we use records we get from pharmacies. Here is how you can help us keep your information correct and up to date:

- **Show your membership card when you get a prescription filled.** To make sure we know about the prescriptions you are filling and what you are paying, show your plan membership card every time you get a prescription filled.
- **Make sure we have the information we need.** There are times you may pay for prescription drugs when we will not automatically get the information we need to keep track of your out-of-pocket costs. To help us keep track of your out-of-pocket costs, you may give us copies of receipts for drugs that you have purchased. (If you are billed for a covered drug, you can ask our plan to pay our share of the cost. For instructions on how to do this, go to Chapter 7, Section 2 of this booklet.) Here are some types of situations when you may want to give us copies of your drug receipts to be sure we have a complete record of what you have spent for your drugs:
 - When you purchase a covered drug at a network pharmacy at a special price or using a discount card that is not part of our plan's benefit.
 - When you made a copayment for drugs that are provided under a drug manufacturer patient assistance program.
 - Any time you have purchased covered drugs at out-of-network pharmacies or other times you have paid the full price for a covered drug under special circumstances.
- **Send us information about the payments others have made for you.** Payments made by certain other individuals and organizations also count toward your out-of-pocket costs and help qualify you for catastrophic coverage. For example, payments made by an AIDS drug assistance program, the Indian Health Service, and most charities count toward your out-of-pocket costs. You should keep a record of these payments and send them to us so we can track your costs.

- **Check the written report we send you.** When you receive a SmartSummary in the mail, please look it over to be sure the information is complete and correct. If you think something is missing from the report, or if you have any questions, please call Customer Care (phone numbers are printed on the back cover of this booklet). Be sure to keep these reports. They are an important record of your drug expenses.

SECTION 4 There is no deductible for Humana Gold Plus H0108-004 (HMO)

Section 4.1 You do not pay a deductible for your Part D drugs

There is no deductible for Humana Gold Plus H0108-004 (HMO). You begin in the Initial Coverage Stage when you fill your first prescription of the year. See Section 5 for information about your coverage in the Initial Coverage Stage.

SECTION 5 During the Initial Coverage Stage, the plan pays its share of your drug costs and you pay your share

Section 5.1 What you pay for a drug depends on the drug and where you fill your prescription
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During the Initial Coverage Stage, the plan pays its share of the cost of your covered prescription drugs, and you pay your share (your copayment or coinsurance amount). Your share of the cost will vary depending on the drug and where you fill your prescription.

The plan has five cost-sharing tiers

Every drug in the plan's Drug Guide is in one of five cost-sharing tiers. In general, the higher the cost-sharing tier number, the higher your cost for the drug:

- **Cost-Sharing Tier 1 – Preferred Generic:** Generic or brand drugs that are available at the lowest cost share for this plan.
- **Cost-Sharing Tier 2 – Non-Preferred Generic:** Generic or brand drugs that Humana offers at a higher cost to you than Tier 1 Preferred Generic drugs.
- **Cost-Sharing Tier 3 – Preferred Brand:** Generic or brand drugs that Humana offers at a lower cost to you than Tier 4 Non-Preferred Brand drugs.
- **Cost-Sharing Tier 4 – Non-Preferred Brand:** Generic or brand drugs that Humana offers at a higher cost to you than Tier 3 Preferred Brand drugs.
- **Cost-Sharing Tier 5 – Specialty:** Some injectables and other high-cost drugs.

To find out which cost-sharing tier your drug is in, look it up in the plan's Drug Guide.

Your pharmacy choices

How much you pay for a drug depends on whether you get the drug from:

- A retail pharmacy that is in our plan's network
- A pharmacy that is not in the plan's network
- A preferred mail-order pharmacy that is in our plan's network

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- A non-preferred mail-order pharmacy that is in our plan's network

For more information about these pharmacy choices and filling your prescriptions, see Chapter 5 in this booklet and the plan's Provider Directory.

Generally, we will cover your prescriptions only if they are filled at one of our network pharmacies. Some of our network pharmacies are also preferred. You may go to either preferred network pharmacies or other network pharmacies to receive your covered prescription drugs. Your costs may be less at preferred pharmacies.

Section 5.2 A table that shows your costs for a one-month supply of a drug

During the Initial Coverage Stage, your share of the cost of a covered drug will be either a copayment or coinsurance.

- **"Copayment"** means that you pay a fixed amount each time you fill a prescription.
- **"Coinsurance"** means that you pay a percent of the total cost of the drug each time you fill a prescription.

As shown in the table below, the amount of the copayment or coinsurance depends on which cost-sharing tier your drug is in. Please note:

- If your covered drug costs less than the copayment amount listed in the chart, you will pay that lower price for the drug. You pay either the full price of the drug or the copayment amount, whichever is lower.
- We cover prescriptions filled at out-of-network pharmacies in only limited situations. Please see Chapter 5, Section 2.5 for information about when we will cover a prescription filled at an out-of-network pharmacy.

Your share of the cost when you get a one-month supply of a covered Part D prescription drug from:

	Retail Pharmacy	Preferred Mail Order Pharmacy	Non-Preferred Mail Order Pharmacy	LTC Pharmacy	OON Pharmacy (Coverage is limited to certain situations; see Chapter 3 for details.)*
Cost-Sharing Tier 1 Preferred Generic	\$5	\$5	\$5	\$5	\$5
Cost-Sharing Tier 2 Non-Preferred Generic	\$10	\$10	\$10	\$10	\$10
Cost-Sharing Tier 3 Preferred Brand	\$45	\$45	\$45	\$45	\$45
Cost-Sharing Tier 4 Non-Preferred Brand	\$95	\$95	\$95	\$95	\$95

	Retail Pharmacy	Preferred Mail Order Pharmacy	Non-Preferred Mail Order Pharmacy	LTC Pharmacy	OOO Pharmacy (Coverage is limited to certain situations; see Chapter 3 for details.)*
Cost-Sharing Tier 5 Specialty	33%	33%	33%	33%	33%

* You pay the in network cost share plus the difference between the in network cost and the out of network cost for covered prescription drugs received from a non network pharmacy.

Section 5.3	If your doctor prescribes less than a full month's supply, you may not have to pay the cost of the entire month's supply
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Typically, you pay a copay to cover a full month's supply of a covered drug. However your doctor can prescribe less than a month's supply of drugs. There may be times when you want to ask your doctor about prescribing less than a month's supply of a drug (for example, when you are trying a medication for the first time that is known to have serious side effects). If your doctor agrees, you will not have to pay for the full month's supply for certain drugs.

The amount you pay when you get less than a full month's supply will depend on whether you are responsible for paying coinsurance (a percentage of the total cost) or a copayment (a flat dollar amount).

- If you are responsible for coinsurance, you pay a percentage of the total cost of the drug. You pay the same percentage regardless of whether the prescription is for a full month's supply or for fewer days. However, because the entire drug cost will be lower if you get less than a full month's supply, the amount you pay will be less.
- If you are responsible for a copayment for the drug, your copayment will be based on the number of days of the drug that you receive. We will calculate the amount you pay per day for your drug (the "daily cost-sharing rate") and multiply it by the number of days of the drug you receive.
 - Here's an example: Let's say the copayment for your drug for a full month's supply (a 30-day supply) is \$30. This means that the amount you pay per day for your drug is \$1. If you receive a 7 days' supply of the drug, your payment will be \$1 per day multiplied by 7 days, for a total payment of \$7.
 - You should not have to pay more per day just because you begin with less than a month's supply. Let's go back to the example above. Let's say you and your doctor agree that the drug is working well and that you should continue taking the drug after your 7 days' supply runs out. If you receive a second prescription for the rest of the month, or 23 days more of the drug, you will still pay \$1 per day, or \$23. Your total cost for the month will be \$7 for your first prescription and \$23 for your second prescription, for a total of \$30 – the same as your copayment would be for a full month's supply.

Daily cost-sharing allows you to make sure a drug works for you before you have to pay for an entire month's supply.

Section 5.4 A table that shows your costs for a long-term (up to a 90-day) supply of a drug

For some drugs, you can get a long-term supply (also called an "extended supply") when you fill your prescription. A long-term supply is up to a 90-day supply. (For details on where and how to get a long-term supply of a drug, see Chapter 5, Section 2.4.)

The table below shows what you pay when you get a long-term (up to a 90-day) supply of a drug.

Please note: If your covered drug costs less than the copayment amount listed in the chart, you will pay that lower price for the drug. You pay either the full price of the drug or the copayment amount, whichever is lower.

Your share of the cost when you get a long-term (90-day) supply of a covered Part D prescription drug from:

	Retail Pharmacy	Preferred Mail Order Pharmacy	Non-Preferred Mail Order Pharmacy
Cost-Sharing Tier 1 Preferred Generic	\$15	\$0	\$15
Cost-Sharing Tier 2 Non-Preferred Generic	\$30	\$0	\$30
Cost-Sharing Tier 3 Preferred Brand	\$135	\$125	\$135
Cost-Sharing Tier 4 Non-Preferred Brand	\$285	\$275	\$285

Cost-Sharing Tier 5 drugs are limited to a 30 day supply

Section 5.5 You stay in the Initial Coverage Stage until your total drug costs for the year reach \$2,850

You stay in the Initial Coverage Stage until the total amount for the prescription drugs you have filled and refilled reaches the **\$2,850 limit for the Initial Coverage Stage**.

Your total drug cost is based on adding together what you have paid and what any Part D plan has paid:

- **What you have paid** for all the covered drugs you have received since you started with your first drug purchase of the year. (See Section 6.2 for more information about how Medicare calculates your out-of-pocket costs.) This includes:
 - The total you paid as your share of the cost for your drugs during the Initial Coverage Stage.
- **What the plan has paid** as its share of the cost for your drugs during the Initial Coverage Stage. (If you were enrolled in a different Part D plan at any time during 2014, the amount that plan paid during the Initial Coverage Stage also counts toward your total drug costs.)

We also provide some over-the-counter medications exclusively for your use. These over-the-counter drugs are provided at no cost to you. To find out which drugs our plan covers, refer to your Drug Guide.

The SmartSummary that we send to you will help you keep track of how much you and the plan have spent for your drugs during the year. Many people do not reach the **\$2,850** limit in a year.

We will let you know if you reach this **\$2,850** amount. If you do reach this amount, you will leave the Initial Coverage Stage and move on to the Coverage Gap Stage.

SECTION 6 During the Coverage Gap Stage, the plan provides some drug coverage

Section 6.1 You stay in the Coverage Gap Stage until your out-of-pocket costs reach \$4,550

After you leave the Initial Coverage Stage, we will continue to provide some prescription drug coverage in the Coverage Gap. For details about which types of drugs are covered and their cost shares, see the charts below.

For drugs we do not provide coverage for in the Coverage Gap, the Medicare Coverage Gap Discount Program provides manufacturer discounts on brand-name drugs. You pay **47.5 percent** of the negotiated price (excluding the dispensing fee and vaccine administration fee, if any) for brand-name drugs. Both the amount you pay and the amount discounted by the manufacturer count toward your out-of-pocket costs as if you had paid them and moves you through the coverage gap.

You also receive some coverage for generic drugs that we do not cover in the Coverage Gap. You pay no more than **72 percent** of the cost for generic drugs and the plan pays the rest. For generic drugs, the amount paid by the plan (**28 percent**) does not count toward your out-of-pocket costs. Only the amount you pay counts and moves you through the coverage gap.

For drugs we do not cover in the Coverage Gap, you continue paying the discounted price for brand-name drugs and no more than **72 percent** of the costs of generic drugs until your yearly out-of-pocket payments reach a maximum amount that Medicare has set. In 2014, that amount is **\$4,550**.

The table below shows what you pay when you get a one-month 30-day supply (or less) of a drug.

	Retail Pharmacy	Preferred Mail Order Pharmacy	Non-Preferred Mail Order Pharmacy	LTC Pharmacy	OON Pharmacy (Coverage is limited to certain situations; see Chapter 3 for details.)*
Cost-Sharing Tier 1					
Home Infusion Drugs	\$5	\$5	\$5	\$5	\$5
All Other Drugs	100%	100%	100%	100%	100%

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	Retail Pharmacy	Preferred Mail Order Pharmacy	Non-Preferred Mail Order Pharmacy	LTC Pharmacy	OON Pharmacy (Coverage is limited to certain situations; see Chapter 3 for details.)*
Cost- Sharing Tier 2					
Home Infusion Drugs	\$10	\$10	\$10	\$10	\$10
All Other Drugs	100%	100%	100%	100%	100%
Cost- Sharing Tier 3					
Home Infusion Drugs	\$45	\$45	\$45	\$45	\$45
All Other Drugs	100%	100%	100%	100%	100%
Cost- Sharing Tier 4					
Home Infusion Drugs	\$95	\$95	\$95	\$95	\$95
All Other Drugs	100%	100%	100%	100%	100%
Cost- Sharing Tier 5					
Home Infusion Drugs	33%	33%	33%	33%	33%
All Other Drugs	100%	100%	100%	100%	100%

* You pay the in network cost share plus the difference between the in network cost and the out of network cost for covered prescription drugs received from a non network pharmacy.

The table below shows what you pay when you get a long-term 90-day supply of a drug.

	Retail Pharmacy	Preferred Mail Order Pharmacy	Non-Preferred Mail Order Pharmacy
Cost-Sharing Tier 1			
Home Infusion Drugs	\$15	\$0	\$15
All Other Drugs	100%	100%	100%

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	Retail Pharmacy	Preferred Mail Order Pharmacy	Non-Preferred Mail Order Pharmacy
Cost-Sharing Tier 2			
Home Infusion Drugs	\$30	\$0	\$30
All Other Drugs	100%	100%	100%
Cost-Sharing Tier 3			
Home Infusion Drugs	\$135	\$125	\$135
All Other Drugs	100%	100%	100%
Cost-Sharing Tier 4			
Home Infusion Drugs	\$285	\$275	\$285
All Other Drugs	100%	100%	100%

Cost-Sharing Tier 5 drugs are limited to a 30 day supply

Medicare has rules about what counts and what does not count as your out-of-pocket costs. When you reach an out-of-pocket limit of **\$4,550**, you leave the Coverage Gap Stage and move on to the Catastrophic Coverage Stage.

Section 6.2 How Medicare calculates your out-of-pocket costs for prescription drugs

Here are Medicare's rules that we must follow when we keep track of your out-of-pocket costs for your drugs.

These payments **are included** in your out-of-pocket costs

When you add up your out-of-pocket costs, **you can include** the payments listed below (as long as they are for Part D covered drugs and you followed the rules for drug coverage that are explained in Chapter 5 of this booklet):

- The amount you pay for drugs when you are in any of the following drug payment stages:
 - The Initial Coverage Stage.
 - The Coverage Gap Stage.
- Any payments you made during this calendar year as a member of a different Medicare prescription drug plan before you joined our plan.

It matters who pays:

- If you make these payments **yourself**, they are included in your out-of-pocket costs.
- These payments are also included if they are made on your behalf by **certain other individuals or organizations**. This includes payments for your drugs made by a friend or relative, by most charities, by AIDS drug assistance programs, or by the Indian Health Service. Payments made by Medicare's "Extra Help" program are also included.
- Some of the payments made by the Medicare Coverage Gap Discount Program are included. The amount the manufacturer pays for your brand-name drugs is included. But the amount the plan pays for your generic drugs is not included.

Moving on to the Catastrophic Coverage Stage:

When you (or those paying on your behalf) have spent a total of **\$4,550** in out-of-pocket costs within the calendar year, you will move from the Coverage Gap Stage to the Catastrophic Coverage Stage.

These payments are **not included** in your out-of-pocket costs

When you add up your out-of-pocket costs, you are **not allowed to include** any of these types of payments for prescription drugs:

- Drugs you buy outside the United States and its territories.
- Drugs that are not covered by our plan.
- Drugs you get at an out-of-network pharmacy that do not meet the plan's requirements for out-of-network coverage.
- Non-Part D drugs, including prescription drugs covered by Part A or Part B and other drugs excluded from coverage by Medicare.
- Payments you make toward prescription drugs not normally covered in a Medicare Prescription Drug Plan.
- Payments made by the plan for your generic drugs while in the Coverage Gap.
- Payments for your drugs that are made by group health plans including employer health plans.
- Payments for your drugs that are made by certain insurance plans and government-funded health programs such as TRICARE and the Veterans Administration.
- Payments for your drugs made by a third-party with a legal obligation to pay for prescription costs (for example, Workers' Compensation).

Reminder: If any other organization such as the ones listed above pays part or all of your out-of-pocket costs for drugs, you are required to tell our plan. Call Customer Care to let us know (phone numbers are printed on the back cover of this booklet).

How can you keep track of your out-of-pocket total?

- **We will help you.** The SmartSummary report we send to you includes the current amount of your out-of-pocket costs (Section 3 in this chapter tells about this report). When you reach a total of **\$4,550** in out-of-pocket costs for the year, this report will tell you that you have left the Coverage Gap Stage and have moved on to the Catastrophic Coverage Stage.
- **Make sure we have the information we need.** Section 3.2 tells what you can do to help make sure that our records of what you have spent are complete and up to date.

SECTION 7 During the Catastrophic Coverage Stage, the plan pays most of the cost for your drugs

Section 7.1	Once you are in the Catastrophic Coverage Stage, you will stay in this stage for the rest of the year
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You qualify for the Catastrophic Coverage Stage when your out-of-pocket costs have reached the **\$4,550** limit for the calendar year. Once you are in the Catastrophic Coverage Stage, you will stay in this payment stage until the end of the calendar year.

During this stage, the plan will pay most of the cost for your drugs.

- **Your share** of the cost for a covered drug will be either coinsurance or a copayment, whichever is the larger amount:
 - either – coinsurance of **5 percent** of the cost of the drug
 - or – **\$2.55** copayment for a generic drug or a drug that is treated like a generic. Or a **\$6.35** copayment for all other drugs.
- **Our plan pays the rest** of the cost.

SECTION 8 Additional benefits information

Section 8.1	Our plan does not offer additional benefits
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There are no additional prescription drug benefits available with this plan.

SECTION 9 What you pay for vaccinations covered by Part D depends on how and where you get them

Section 9.1	Our plan has separate coverage for the Part D vaccine medication itself and for the cost of giving you the vaccination shot
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Our plan provides coverage of a number of Part D vaccines. We also cover vaccines that are considered medical benefits. You can find out about coverage of these vaccines by going to the Medical Benefits Chart in Chapter 4, Section 2.1.

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There are two parts to our coverage of Part D vaccinations:

- The first part of coverage is the cost of **the vaccine medication itself**. The vaccine is a prescription medication.
- The second part of coverage is for the cost of **giving you the vaccination shot**. (This is sometimes called the "administration" of the vaccine.)

What do you pay for a Part D vaccination?

What you pay for a Part D vaccination depends on three things:

- 1. The type of vaccine** (what you are being vaccinated for).
 - Some vaccines are considered medical benefits. You can find out about your coverage of these vaccines by going to Chapter 4, Medical Benefits Chart (what is covered and what you pay).
 - Other vaccines are considered Part D drugs. You can find these vaccines listed in the plan's Drug Guide (Formulary).
- 2. Where you get the vaccine medication.**
- 3. Who gives you the vaccination shot.**

What you pay at the time you get the Part D vaccination can vary depending on the circumstances. For example:

- Sometimes when you get your vaccination shot, you will have to pay the entire cost for both the vaccine medication and for getting the vaccination shot. You can ask our plan to pay you back for our share of the cost.
- Other times, when you get the vaccine medication or the vaccination shot, you will pay only your share of the cost.

To show how this works, here are three common ways you might get a Part D vaccination shot. Remember you are responsible for all of the costs associated with vaccines (including their administration) during the Coverage Gap Stage of your benefit.

Situation 1: You buy the Part D vaccine at the pharmacy and you get your vaccination shot at the network pharmacy. (Whether you have this choice depends on where you live. Some states do not allow pharmacies to administer a vaccination.)

- You will have to pay the pharmacy the amount of your copayment or coinsurance for the vaccine and administration of the vaccine.

Situation 2: You get the Part D vaccination at your doctor's office.

- When you get the vaccination, you will pay for the entire cost of the vaccine and its administration.
- You can then ask our plan to pay our share of the cost by using the procedures that are described in Chapter 7 of this booklet (Asking us to pay our share of a bill you have received for covered medical services or drugs).
- You will be reimbursed the amount you paid less your normal coinsurance or copayment for the vaccine (including administration) less any difference between the amount the doctor charges and what we normally pay. (If you get "Extra Help," we will reimburse you for this difference.)

- Situation 3:** You buy the Part D vaccine at your pharmacy, and then take it to your doctor's office where they give you the vaccination shot.
- You will have to pay the pharmacy the amount of your coinsurance or copayment for the vaccine itself.
 - When your doctor gives you the vaccination shot, you will pay the entire cost for this service. You can then ask our plan to pay our share of the cost by using the procedures described in Chapter 7 of this booklet.
 - You will be reimbursed the amount charged by the doctor for administering the vaccine less any difference between the amount the doctor charges and what we normally pay. (If you get "Extra Help", we will reimburse you for this difference.)

Section 9.2 You may want to call us at Customer Care before you get a vaccination

The rules for coverage of vaccinations are complicated. We are here to help. We recommend that you call us first at Customer Care whenever you are planning to get a vaccination (phone numbers for Customer Care are printed on the back cover of this booklet).

- We can tell you about how your vaccination is covered by our plan and explain your share of the cost.
- We can tell you how to keep your own cost down by using providers and pharmacies in our network.
- If you are not able to use a network provider and pharmacy, we can tell you what you need to do to get payment from us for our share of the cost.

SECTION 10 Do you have to pay the Part D "late enrollment penalty"?

Section 10.1 What is the Part D "late enrollment penalty"?

Note: If you receive "Extra Help" from Medicare to pay for your prescription drugs, the late enrollment penalty rules do not apply to you. You will not pay a late enrollment penalty, even if you go without "creditable" prescription drug coverage.

You may pay a financial penalty if you did not enroll in a plan offering Medicare Part D drug coverage when you first became eligible for this drug coverage or you experienced a continuous period of 63 days or more when you didn't have creditable prescription drug coverage. ("Creditable prescription drug coverage" is coverage that meets Medicare's minimum standards since it is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage.) The amount of the penalty depends on how long you waited to enroll in a creditable prescription drug coverage plan any time after the end of your initial enrollment period or how many full calendar months you went without creditable prescription drug coverage. You will have to pay this penalty for as long as you have Part D coverage.

When you first enroll in Humana Gold Plus H0108-004 (HMO), we let you know the amount of the penalty. Your late enrollment penalty is considered your plan premium. If you do not pay your late enrollment penalty, you could be disenrolled from the plan.

Section 10.2 How much is the Part D late enrollment penalty?

Medicare determines the amount of the penalty. Here is how it works:

- First count the number of full months that you delayed enrolling in a Medicare drug plan, after you were eligible to enroll. Or count the number of full months in which you did not have creditable prescription drug coverage, if the break in coverage was 63 days or more. The penalty is **1 percent** for every month that you didn't have creditable coverage. For example, if you go 14 months without coverage, the penalty will be **14 percent**.
- Then Medicare determines the amount of the average monthly premium for Medicare drug plans in the nation from the previous year. For 2013, this average premium amount was **\$31.17**. This amount may change for 2014.
- To calculate your monthly penalty, you multiply the penalty percentage and the average monthly premium and then round it to the nearest 10 cents. In the example here it would be **14 percent** times **\$31.17**, which equals **\$4.36**. This rounds to **\$4.40**. This amount would be added **to the monthly premium for someone with a late enrollment penalty**.

There are three important things to note about this monthly late enrollment penalty:

- First, **the penalty may change each year**, because the average monthly premium can change each year. If the national average premium (as determined by Medicare) increases, your penalty will increase.
- Second, **you will continue to pay a penalty** every month for as long as you are enrolled in a plan that has Medicare Part D drug benefits.
- Third, if you are under 65 and currently receiving Medicare benefits, the late enrollment penalty will reset when you turn 65. After age 65, your late enrollment penalty will be based only on the months that you don't have coverage after your initial enrollment period for aging into Medicare.

Section 10.3 In some situations, you can enroll late and not have to pay the penalty

Even if you have delayed enrolling in a plan offering Medicare Part D coverage when you were first eligible, sometimes you do not have to pay the late enrollment penalty.

You will not have to pay a penalty for late enrollment if you are in any of these situations:

- If you already have prescription drug coverage that is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage. Medicare calls this **"creditable drug coverage."** Please note:
 - Creditable coverage could include drug coverage from a former employer or union, TRICARE, or the Department of Veterans Affairs. Your insurer or your human resources department will tell you each year if your drug coverage is creditable coverage. This information may be sent to you in a letter or included in a newsletter from the plan. Keep this information, because you may need it if you join a Medicare drug plan later.
 - > Please note: If you receive a "certificate of creditable coverage" when your health coverage ends, it may not mean your prescription drug coverage was creditable. The notice must state that you had "creditable" prescription drug coverage that expected to pay as much as Medicare's standard prescription drug plan pays.
 - The following are not creditable prescription drug coverage: prescription drug discount cards, free clinics, and drug discount websites.
 - For additional information about creditable coverage, please look in your Medicare & You 2014 Handbook or call Medicare at 1-800-MEDICARE (1-800-633-4227). TTY users call 1-877-486-2048. You can call these numbers for free, 24 hours a day, 7 days a week.
- If you were without creditable coverage, but you were without it for less than 63 days in a row.
- If you are receiving "Extra Help" from Medicare.

Section 10.4 What can you do if you disagree about your late enrollment penalty?

If you disagree about your late enrollment penalty, you or your representative can ask for a review of the decision about your late enrollment penalty. Generally, you must request this review **within 60 days** from the date on the letter you receive stating you have to pay a late enrollment penalty. Call Customer Care to find out more about how to do this (phone numbers are printed on the back cover of this booklet).

Important: Do not stop paying your late enrollment penalty while you're waiting for a review of the decision about your late enrollment penalty. If you do, you could be disenrolled for failure to pay your plan premiums.

SECTION 11 Do you have to pay an extra Part D amount because of your income?

Section 11.1 Who pays an extra Part D amount because of income?

Most people pay a standard monthly Part D premium. However, some people pay an extra amount because of their yearly income. If your income is **\$85,000** or above for an individual (or married individuals filing separately) or **\$170,000** or above for married couples, you must pay an extra amount directly to the government for your Medicare Part D coverage.

If you have to pay an extra amount, Social Security, not your Medicare plan, will send you a letter telling you what that extra amount will be and how to pay it. The extra amount will be withheld from your Social Security, Railroad Retirement Board, or Office of Personnel Management benefit check, no matter how you usually pay your plan premium, unless your monthly benefit isn't enough to cover the extra amount owed. If your benefit check isn't enough to cover the extra amount, you will get a bill from Medicare. **You must pay the extra amount to the government. It cannot be paid with your monthly plan premium.**

Section 11.2 How much is the extra Part D amount?

If your modified adjusted gross income (MAGI) as reported on your IRS tax return is above a certain amount, you will pay an extra amount in addition to your monthly plan premium.

The chart below shows the extra amount based on your income.

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Chapter 6: What you pay for your Part D prescription drugs

If you filed an individual tax return and your income in 2012 was:	If you were married but filed a separate tax return and your income in 2012 was:	If you filed a joint tax return and your income in 2012 was:	This is the monthly cost of your extra Part D amount (to be paid in addition to your plan premium)
Equal to or less than \$85,000	Equal to or less than \$85,000	Equal to or less than \$170,000	\$0
Greater than \$85,000 and less than or equal to \$107,000		Greater than \$170,000 and less than or equal to \$214,000	\$12.10
Greater than \$107,000 and less than or equal to \$160,000		Greater than \$214,000 and less than or equal to \$320,000	\$31.10
Greater than \$160,000 and less than or equal to \$214,000	Greater than \$85,000 and less than or equal to \$129,000	Greater than \$320,000 and less than or equal to \$428,000	\$50.20
Greater than \$214,000	Greater than \$129,000	Greater than \$428,000	\$69.30

Section 11.3 What can you do if you disagree about paying an extra Part D amount?

If you disagree about paying an extra amount because of your income, you can ask Social Security to review the decision. To find out more about how to do this, contact Social Security at 1-800-772-1213 (TTY 1-800-325-0778).

Section 11.4 What happens if you do not pay the extra Part D amount?

The extra amount is paid directly to the government (not your Medicare plan) for your Medicare Part D coverage. If you are required to pay the extra amount and you do not pay it, you will be disenrolled from the plan and lose prescription drug coverage.

Chapter 7. Asking us to pay our share of a bill you have received for covered medical services or drugs

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SECTION 4 Other situations in which you should save your receipts and send copies to us

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SECTION 1 Situations in which you should ask us to pay our share of the cost of your covered services or drugs

Section 1.1 If you pay our plan's share of the cost of your covered services or drugs, or if you receive a bill, you can ask us for payment

Sometimes when you get medical care or a prescription drug, you may need to pay the full cost right away. Other times, you may find that you have paid more than you expected under the coverage rules of the plan. In either case, you can ask our plan to pay you back (paying you back is often called “reimbursing” you). It is your right to be paid back by our plan whenever you've paid more than your share of the cost for medical services or drugs that are covered by our plan.

There may also be times when you get a bill from a provider for the full cost of medical care you have received. In many cases, you should send this bill to us instead of paying it. We will look at the bill and decide whether the services should be covered. If we decide they should be covered, we will pay the provider directly.

Here are examples of situations in which you may need to ask our plan to pay you back or to pay a bill you have received:

1. When you've received emergency or urgently needed medical care from a provider who is not in our plan's network

You can receive emergency services from any provider, whether or not the provider is a part of our network. When you receive emergency or urgently needed care from a provider who is not part of our network, you are only responsible for paying your share of the cost, not for the entire cost. You should ask the provider to bill the plan for our share of the cost.

- If you pay the entire amount yourself at the time you receive the care, you need to ask us to pay you back for our share of the cost. Send us the bill, along with documentation of any payments you have made.
- At times you may get a bill from the provider asking for payment that you think you do not owe. Send us this bill, along with documentation of any payments you have already made.
 - If the provider is owed anything, we will pay the provider directly.
 - If you have already paid more than your share of the cost for the service, we will determine how much you owed and pay you back for our share of the cost.

2. When a network provider sends you a bill you think you should not pay

Network providers should always bill the plan directly, and ask you only for your share of the cost. But sometimes they make mistakes, and ask you to pay more than your share.

- You only have to pay your cost-sharing amount when you get services covered by our plan. We do not allow providers to add additional separate charges, called “balance billing.” This protection (that you never pay more than your cost-sharing amount) applies even if we pay the provider less than the provider charges for a service and even if there is a dispute and we don't pay certain provider charges. For more information about “balance billing,” go to Chapter 4, Section 1.3.
- Whenever you get a bill from a network provider that you think is more than you should pay, send us the bill. We will contact the provider directly and resolve the billing problem.
- If you have already paid a bill to a network provider, but you feel that you paid too much, send us the bill along with documentation of any payment you have made and ask us to pay you back the difference between the amount you paid and the amount you owed under the plan.

3. If you are retroactively enrolled in our plan

Sometimes a person's enrollment in the plan is retroactive. (Retroactive means that the first day of their enrollment has already passed. The enrollment date may even have occurred last year.)

If you were retroactively enrolled in our plan and you paid out-of-pocket for any of your covered services or drugs after your enrollment date, you can ask us to pay you back for our share of the costs. You will need to submit paperwork for us to handle the reimbursement.

- Please call Customer Care for additional information about how to ask us to pay you back and deadlines for making your request. (Phone numbers for Customer Care are printed on the back cover of this booklet.)

4. When you use an out-of-network pharmacy to get a prescription filled

If you go to an out-of-network pharmacy and try to use your membership card to fill a prescription, the pharmacy may not be able to submit the claim directly to us. When that happens, you will have to pay the full cost of your prescription. (We cover prescriptions filled at out-of-network pharmacies only in a few special situations. Please go to Chapter 5, Sec. 2.5 to learn more.)

- Save your receipt and send a copy to us when you ask us to pay you back for our share of the cost.

5. When you pay the full cost for a prescription because you don't have your plan membership card with you

If you do not have your plan membership card with you, you can ask the pharmacy to call the plan or to look up your plan enrollment information. However, if the pharmacy cannot get the enrollment information they need right away, you may need to pay the full cost of the prescription yourself.

- Save your receipt and send a copy to us when you ask us to pay you back for our share of the cost.

6. When you pay the full cost for a prescription in other situations

You may pay the full cost of the prescription because you find that the drug is not covered for some reason.

- For example, the drug may not be on the plan's Prescription Drug Guide (Formulary); or it could have a requirement or restriction that you didn't know about or don't think should apply to you. If you decide to get the drug immediately, you may need to pay the full cost for it.
- Save your receipt and send a copy to us when you ask us to pay you back. In some situations, we may need to get more information from your doctor in order to pay you back for our share of the cost.

All of the examples above are types of coverage decisions. This means that if we deny your request for payment, you can appeal our decision. Chapter 9 of this booklet (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)) has information about how to make an appeal.

SECTION 2 How to ask us to pay you back or to pay a bill you have received

Section 2.1 How and where to send us your request for payment

Send us your request for payment, along with your bill and documentation of any payment you have made. It's a good idea to make a copy of your bill and receipts for your records.

Mail your request for payment together with any bills or receipts to us at this address:

Humana, P.O. Box 14168, Lexington, KY 40512-4168

Contact Customer Care if you have any questions (phone numbers are printed on the back cover of this booklet). If you don't know what you should have paid, or you receive bills and you don't know what to do about those bills, we can help. You can also call if you want to give us more information about a request for payment you have already sent to us.

SECTION 3 We will consider your request for payment and say yes or no

Section 3.1 We check to see whether we should cover the service or drug and how much we owe

When we receive your request for payment, we will let you know if we need any additional information from you. Otherwise, we will consider your request and make a coverage decision.

- If we decide that the medical care or drug is covered and you followed all the rules for getting the care or drug, we will pay for our share of the cost. If you have already paid for the service or drug, we will mail your reimbursement of our share of the cost to you. If you have not paid for the service or drug yet, we will mail the payment directly to the provider. (Chapter 3 explains the rules you need to follow for getting your medical services covered. Chapter 5 explains the rules you need to follow for getting your Part D prescription drugs covered.)
- If we decide that the medical care or drug is not covered, or you did not follow all the rules, we will not pay for our share of the cost. Instead, we will send you a letter that explains the reasons why we are not sending the payment you have requested and your rights to appeal that decision.

Section 3.2 If we tell you that we will not pay for all or part of the medical care or drug, you can make an appeal

If you think we have made a mistake in turning down your request for payment or you don't agree with the amount we are paying, you can make an appeal. If you make an appeal, it means you are asking us to change the decision we made when we turned down your request for payment.

For the details on how to make this appeal, go to Chapter 9 of this booklet (What to do if you have a problem or complaint (coverage decisions, appeals, complaints)). The appeals process is a formal process with detailed procedures and important deadlines. If making an appeal is new to you, you will find it helpful to start by reading Section 4 of Chapter 9. Section 4 is an introductory section that explains the process for coverage decisions and appeals and gives definitions of terms such as "appeal." Then after you have read Section 4, you can go to the section in Chapter 9 that tells what to do for your situation:

- If you want to make an appeal about getting paid back for a medical service, go to Section 5.3 in Chapter 9.
- If you want to make an appeal about getting paid back for a drug, go to Section 6.5 of Chapter 9.

SECTION 4 Other situations in which you should save your receipts and send copies to us

Section 4.1 In some cases, you should send copies of your receipts to us to help us track your out-of-pocket drug costs

There are some situations when you should let us know about payments you have made for your drugs. In these cases, you are not asking us for payment. Instead, you are telling us about your payments so that we can calculate your out-of-pocket costs correctly. This may help you to qualify for the Catastrophic Coverage Stage more quickly.

Here are two situations when you should send us copies of receipts to let us know about payments you have made for your drugs:

1. When you buy the drug for a price that is lower than our price

Sometimes when you are in the Coverage Gap Stage you can buy your drug **at a network pharmacy** for a price that is lower than our price.

- For example, a pharmacy might offer a special price on the drug. Or you may have a discount card that is outside our benefit that offers a lower price.
- Unless special conditions apply, you must use a network pharmacy in these situations and your drug must be in our Drug Guide.
- Save your receipt and send a copy to us so that we can have your out-of-pocket expenses count toward qualifying you for the Catastrophic Coverage Stage.
- **Please note:** If you are in the Coverage Gap Stage, we will not pay for any share of these drug costs. But sending a copy of the receipt allows us to calculate your out-of-pocket costs correctly and may help you qualify for the Catastrophic Coverage Stage more quickly.

2. When you get a drug through a patient assistance program offered by a drug manufacturer

Some members are enrolled in a patient assistance program offered by a drug manufacturer that is outside the plan benefits. If you get any drugs through a program offered by a drug manufacturer, you may pay a copayment to the patient assistance program.

- Save your receipt and send a copy to us so that we can have your out-of-pocket expenses count toward qualifying you for the Catastrophic Coverage Stage.
- **Please note:** Because you are getting your drug through the patient assistance program and not through the plan's benefits, we will not pay for any share of these drug costs. But sending a copy of the receipt allows us to calculate your out-of-pocket costs correctly and may help you qualify for the Catastrophic Coverage Stage more quickly.

Since you are not asking for payment in the two cases described above, these situations are not considered coverage decisions. Therefore, you cannot make an appeal if you disagree with our decision.

Chapter 8. Your rights and responsibilities

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SECTION 1 Our plan must honor your rights as a member of the plan

Section 1.1	We must provide information in a way that works for you (in languages other than English, in Braille, in large print, or other alternative formats, etc.)
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To get information from us in a way that works for you, please call Customer Care (phone numbers are printed on the back cover of this booklet).

Our plan has people and free language interpreter services available to answer questions from non-English speaking members. We can also give you information in Braille, in large print, or other alternative formats if you need it. If you are eligible for Medicare because of a disability, we are required to give you information about the plan's benefits that is accessible and appropriate for you.

If you have any trouble getting information from our plan because of problems related to language or a disability, please call Medicare at 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week, and tell them that you want to file a complaint. TTY users call 1-877-486-2048.

Para obtener información de una forma que se ajuste a sus necesidades, llame al departamento de Atención al Cliente (los números de teléfono están en la contraportada de este manual).

Nuestro plan cuenta con personal y servicios gratuitos de intérpretes de otros idiomas disponibles para responder preguntas de afiliados que no hablan inglés. También podemos darle información en Braille, en letra grande o en otros formatos alternativos en caso de ser necesario. Si usted es elegible para Medicare por una discapacidad, se nos exige darle información sobre los beneficios del plan que sea accesible y apropiada para usted.

Si se le dificulta obtener información de nuestro plan debido a problemas relacionados con el idioma o una discapacidad, llame a Medicare al 1-800-MEDICARE (1-800-633-4227), 24 horas del día, 7 días de la semana, y díganos que quiere presentar una queja. Los usuarios de TTY deben llamar al 1-877-486-2048.

Section 1.2	We must treat you with fairness and respect at all times
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Our plan must obey laws that protect you from discrimination or unfair treatment. **We do not discriminate** based on a person's race, ethnicity, national origin, religion, gender, age, mental or physical disability, health status, claims experience, medical history, genetic information, evidence of insurability, or geographic location within the service area.

If you want more information or have concerns about discrimination or unfair treatment, please call the Department of Health and Human Services' **Office for Civil Rights** 1-800-368-1019 (TTY 1-800-537-7697) or your local Office for Civil Rights.

If you have a disability and need help with access to care, please call Customer Care (phone numbers are printed on the back cover of this booklet). If you have a complaint, such as a problem with wheelchair access, Customer Care can help.

Section 1.3 We must ensure that you get timely access to your covered services and drugs

As a member of our plan, you have the right to choose a primary care physician (PCP) in the plan's network to provide and arrange for your covered services (Chapter 3 explains more about this). Call Customer Care to learn which doctors are accepting new patients (phone numbers are printed on the back cover of this booklet). You also have the right to go to a women's health specialist (such as a gynecologist) without a referral. As a plan member, you have the right to get appointments and covered services from the plan's network of providers within a reasonable amount of time. This includes the right to get timely services from specialists when you need that care. You also have the right to get your prescriptions filled or refilled at any of our network pharmacies without long delays.

If you think that you are not getting your medical care or Part D drugs within a reasonable amount of time, Chapter 9, Section 10 of this booklet tells what you can do. (If we have denied coverage for your medical care or drugs and you don't agree with our decision, Chapter 9, Section 4 tells what you can do.)

Section 1.4 We must protect the privacy of your personal health information

Federal and state laws protect the privacy of your medical records and personal health information. We protect your personal health information as required by these laws.

- Your "personal health information" includes the personal information you gave us when you enrolled in this plan, as well as your medical records and other medical and health information.
- The laws that protect your privacy give you rights related to getting information and controlling how your health information is used. We give you a written notice, called a "Notice of Privacy Practice," that tells about these rights and explains how we protect the privacy of your health information.

How do we protect the privacy of your health information?

- We make sure that unauthorized people don't see or change your records.
- In most situations, if we give your health information to anyone who isn't providing your care or paying for your care, we are required to get written permission from you first. Written permission can be given by you or by someone you have given legal power to make decisions for you.
- There are certain exceptions that do not require us to get your written permission first. These exceptions are allowed or required by law.
 - For example, we are required to release health information to government agencies that are checking on quality of care.
 - Because you are a member of our plan through Medicare, we are required to give Medicare your health information, including information about your Part D prescription drugs. If Medicare releases your information for research or other uses, this will be done according to federal statutes and regulations.

You can see the information in your records and know how it has been shared with others

You have the right to look at your medical records held at the plan, and to get a copy of your records. We are allowed to charge you a fee for making copies. You also have the right to ask us to make additions or corrections to your medical records. If you ask us to do this, we will work with your healthcare provider to decide whether the changes should be made.

You have the right to know how your health information has been shared with others for any purposes that are not routine.

If you have questions or concerns about the privacy of your personal health information, please call Customer Care (phone numbers are printed on the back cover of this booklet).

Notice of Privacy Practices for your personal health information

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The privacy of your personal and health information is important. You don't need to do anything unless you have a request or complaint.

We reserve the right to change our privacy practices and the terms of this notice at any time, as allowed by law. This includes the right to make changes in our privacy practices and the revised terms of our notice effective for all personal and health information we maintain. This includes information we created or received before we made the changes. When we make a significant change in our privacy practices, we will change this notice and send the notice to our health plan subscribers.

What is personal and health information?

Personal and health information - from now on referred to as "information" - includes both medical information and individually identifiable information, like your name, address, telephone number, or Social Security number. The term "information" in this notice includes any personal and health information created or received by a healthcare provider or health plan that relates to your physical or mental health or condition, providing healthcare to you, or the payment for such healthcare. We protect this information in all formats including electronic, written, and oral information.

How do we protect your information?

In keeping with federal and state laws and our own policy, we have a responsibility to protect the privacy of your information. We have safeguards in place to protect your information in various ways including:

- Limiting who may see your information
- Limiting how we use or disclose your information
- Informing you of our legal duties about your information
- Training our associates about company privacy policies and procedures

How do we use and disclose your information?

We must use and disclose your information:

- To you or someone who has the legal right to act on your behalf
- To the Secretary of the Department of Health and Human Services
- Where required by law

We have the right to use and disclose your information:

- To a doctor, a hospital, or other healthcare provider so you can receive medical care
- For payment activities, including claims payment for covered services provided to you by healthcare providers and for health plan premium payments
- For healthcare operation activities including processing your enrollment, responding to your inquiries and requests for services, coordinating your care, resolving disputes, conducting medical management, improving quality, reviewing the competence of healthcare professionals, and determining premiums
- For performing underwriting activities. However, we will not use any results of genetic testing or ask questions regarding family history.
- To your plan sponsor to permit them to perform plan administration functions such as eligibility, enrollment and disenrollment activities. We may share summary level health information about you with your plan sponsor in certain situations such as to allow your plan sponsor to obtain bids from other health plans. We will not share

detailed health information to your plan sponsor unless you provide us your permission or your plan sponsor has certified they agree to maintain the privacy of your information.

- To contact you with information about health-related benefits and services, appointment reminders, or about treatment alternatives that may be of interest to you if you have not opted out as described below
- To your family and friends if you are unavailable to communicate, such as in an emergency
- To your family and friends or any other person you identify, provided the information is directly relevant to their involvement with your health care or payment for that care. For example, if a family member or a caregiver calls us with prior knowledge of a claim, we may confirm whether or not the claim has been received and paid.
- To provide payment information to the subscriber for Internal Revenue Service substantiation
- To public health agencies if we believe there is a serious health or safety threat
- To appropriate authorities when there are issues about abuse, neglect, or domestic violence
- In response to a court or administrative order, subpoena, discovery request, or other lawful process
- For law enforcement purposes, to military authorities, and as otherwise required by law
- To assist in disaster relief efforts
- For compliance programs and health oversight activities
- To fulfill our obligations under any workers' compensation law or contract
- To avert a serious and imminent threat to your health or safety or the health or safety of others
- For research purposes in limited circumstances
- For procurement, banking, or transplantation of organs, eyes, or tissue
- To a coroner, medical examiner, or funeral director

Will we use your information for purposes not described in this notice?

In all situations other than described in this notice, we will request your written permission before using or disclosing your information. You may revoke your permission at any time by notifying us in writing. We will not use or disclose your information for any reason not described in this notice without your permission. The following uses and disclosures will require an authorization:

- Most uses and disclosures of psychotherapy notes
- Marketing purposes
- Sale of protected health information

What do we do with your information when you are no longer a member or you do not obtain coverage through us?

Your information may continue to be used for purposes described in this notice when your membership is terminated or you do not obtain coverage through us. After the required legal retention period, we destroy the information following strict procedures to maintain the confidentiality.

What are my rights concerning my information?

The following are your rights with respect to your information: We are committed to responding to your rights request in a timely manner:

- Access – You have the right to review and obtain a copy of your information that may be used to make decisions about you, such as claims and case or medical management records. You also may receive a summary of this health information. If you request copies, we may charge you a fee for each page, a per hour charge for staff time to locate and copy your information, and postage.
- Adverse Underwriting Decision – You have the right to be provided a reason for denial or adverse underwriting decision if we decline your application for insurance. *
- Alternate Communications – You have the right to receive confidential communications of information in a different manner or at a different place to avoid a life threatening situation. We will accommodate your request if it is reasonable.
- Amendment – You have the right to request an amendment of information we maintain about you if you believe the information is wrong or incomplete. We may deny your request if we did not create the information,

we do not maintain the information, or the information is correct and complete. If we deny your request, we will give you a written explanation of the denial.

- **Disclosure** – You have the right to receive a listing of instances in which we or our business associates have disclosed your information for purposes other than treatment, payment, health plan operations, and certain other activities. We maintain this information and make it available to you for a period of six years at your request. If you request this list more than once in a 12-month period, we may charge you a reasonable, cost-based fee for responding to these additional requests.
- **Notice** – You have the right to receive a written copy of this notice any time you request.
- **Restriction** – You have the right to ask to restrict uses or disclosures of your information. We are not required to agree to these restrictions, but if we do, we will abide by our agreement. You also have the right to agree to or terminate a previously submitted restriction.

What types of communications can I opt out of that are made to me?

- **Appointment reminders**
- **Treatment alternatives or other health-related benefits**
- **or services**
- **Fundraising activities**

How do I exercise my rights or obtain a copy of this notice?

All of your privacy rights can be exercised by obtaining the applicable privacy rights request forms. You may obtain any of the forms by:

- Contacting us at 1-866-861-2762 at any time
- Accessing our website at **Humana.com** and going to the Privacy Practices link
- E-mailing us at privacyoffice@humana.com

* This right applies only to our Massachusetts residents in accordance with state regulations.

Send completed request form to:

Humana Inc.
Privacy Office 003/10911
101 E. Main Street
Louisville, KY 40202

What should I do if I believe my privacy has been violated?

If you believe your privacy has been violated in any way, you may file a complaint with us by calling us at: 1-866-861-2762 any time.

You may also submit a written complaint to the U.S. Department of Health and Human Services, Office of Civil Rights (OCR). We will give you the appropriate OCR regional address on request. You also have the option to e-mail your complaint to OCRComplaint@hhs.gov. We support your right to protect the privacy of your personal and health information. We will not retaliate in any way if you elect to file a complaint with us or with the U.S. Department of Health and Human Services.

We follow all federal and state laws, rules, and regulations addressing the protection of personal and health information. In situations when federal and state laws, rules, and regulations conflict, we follow the law, rule, or regulation which provides greater member protection.

What will happen if my private information is used or disclosed inappropriately?

You have a right to receive a notice that a breach has resulted in your unsecured private information being inappropriately used or disclosed. We will notify you in a timely manner if such a breach occurs.

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Chapter 8: Your rights and responsibilities

The following affiliates and subsidiaries also adhere to our privacy policies and procedures:

American Dental Plan of North Carolina, Inc.
American Dental Providers of Arkansas, Inc.
Arcadian Health Plan, Inc.
CarePlus Health Plans, Inc.
Cariten Health Plan, Inc.
Cariten Insurance Company
CHA HMO, Inc.
CompBenefits Company
CompBenefits Dental, Inc.
CompBenefits Insurance Company
CompBenefits of Alabama, Inc.
CompBenefits of Georgia, Inc.
CorpHealth, Inc. dba LifeSynch
Corphealth Provider Link, Inc.
DentiCare, Inc.
Emphesys, Inc.
Emphesys Insurance Company
HumanaDental Insurance Company
Humana AdvantageCare Plan, Inc. fna Metcare Health Plans, Inc.
Humana Benefit Plan of Illinois, Inc. fna OSF Health Plans, Inc.
Humana Employers Health Plan of Georgia, Inc.
Humana Health Benefit Plan of Louisiana, Inc.
Humana Health Company of New York, Inc.
Humana Health Insurance Company of Florida, Inc.
Humana Health Plan of California, Inc.
Humana Health Plan of Ohio, Inc.
Humana Health Plan of Texas, Inc.
Humana Health Plan, Inc.
Humana Health Plans of Puerto Rico, Inc.
Humana Insurance Company
Humana Insurance Company of Kentucky
Humana Insurance Company of New York
Humana Insurance of Puerto Rico, Inc.
Humana MarketPOINT, Inc.
Humana MarketPOINT of Puerto Rico, Inc.
Humana Medical Plan, Inc.
Humana Medical Plan of Michigan, Inc.
Humana Medical Plan of Pennsylvania, Inc.
Humana Medical Plan of Utah, Inc.
Humana Pharmacy, Inc.
Humana Regional Health Plan, Inc.
Humana Wisconsin Health Organization Insurance Corporation
Managed Care Indemnity, Inc.
Preferred Health Partnership of Tennessee, Inc.
The Dental Concern, Inc.
The Dental Concern, Ltd.

Section 1.5	We must give you information about the plan, its network of providers, and your covered services
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As a member of Humana Gold Plus H0108-004 (HMO), you have the right to get several kinds of information from us. (As explained above in Section 1.1, you have the right to get information from us in a way that works for you. This includes getting the information in languages other than English and in large print or other alternative formats.)

If you want any of the following kinds of information, please call Customer Care (phone numbers are printed on the back cover of this booklet):

- **Information about our plan.** This includes, for example, information about the plan's financial condition. It also includes information about the number of appeals made by members and the plan's performance ratings, including how it has been rated by plan members and how it compares to other Medicare health plans.
- **Information about our network providers including our network pharmacies.**
 - For example, you have the right to get information from us about the qualifications of the providers and pharmacies in our network and how we pay the providers in our network.
 - For a list of the providers in the plan's network, see the Provider Directory.
 - For a list of pharmacies in the plan's network, see the Provider Directory.
 - For more detailed information about our providers or pharmacies, you can call Customer Care (phone numbers are printed on the back cover of this booklet) or visit our website at **Humana.com**.
- **Information about your coverage and the rules you must follow when using your coverage.**
 - In Chapters 3 and 4 of this booklet, we explain what medical services are covered for you, any restrictions to your coverage, and what rules you must follow to get your covered medical services.
 - To get the details on your Part D prescription drug coverage, see Chapters 5 and 6 of this booklet plus the plan's Prescription Drug Guide (Formulary). These chapters, together with the Prescription Drug Guide (Formulary), tell you what drugs are covered and explain the rules you must follow and the restrictions to your coverage for certain drugs.
 - We have special programs to help you if you have complicated medical conditions or certain chronic conditions. Our case management program offers supportive services to members with complicated medical conditions, or those who have been hospitalized. A Humana nurse helps you navigate the health care system and assists in coordinating services. Other programs help people manage health conditions like diabetes, heart failure, COPD and other illnesses. If you would like more information about these special health programs you may call the Health Planning and Support team at 1-800-491-4164.
 - If you have questions about the rules or restrictions, please call Customer Care (phone numbers are printed on the back cover of this booklet).
- **Information about why something is not covered and what you can do about it.**
 - If a medical service or Part D drug is not covered for you, or if your coverage is restricted in some way, you can ask us for a written explanation. You have the right to this explanation even if you received the medical service or drug from an out-of-network provider or pharmacy.
 - If you are not happy or if you disagree with a decision we make about what medical care or Part D drug is covered for you, you have the right to ask us to change the decision. You can ask us to change the decision by making an appeal. For details on what to do if something is not covered for you in the way you think it should be covered, see Chapter 9 of this booklet. It gives you the details about how to make an appeal if you want us to change our decision. (Chapter 9 also tells about how to make a complaint about quality of care, waiting times, and other concerns.)
 - If you want to ask our plan to pay our share of a bill you have received for medical care or a Part D prescription drug, see Chapter 7 of this booklet.

We have a Quality Improvement (QI) program that focuses on clinical and preventive care and member service functions of the health plan. You may obtain a written Quality Improvement Progress Report that contains information on our Quality Improvement (QI) Program and how we are meeting our QI Program goals. It is available on Humana's website under Humana Medicare Plans. To request a printed copy or to provide input into the QI Program, mail a request to the following address: Humana Quality Operations and Compliance Department, Progress Report, 321 West Main, WFP 20, Louisville, KY 40202.

Section 1.6 We must support your right to make decisions about your care

You have the right to know your treatment options and participate in decisions about your health care

You have the right to get full information from your doctors and other health care providers when you go for medical care. Your providers must explain your medical condition and your treatment choices in a way that you can understand.

You also have the right to participate fully in decisions about your health care. To help you make decisions with your doctors about what treatment is best for you, your rights include the following:

- **To know about all of your choices.** This means that you have the right to be told about all of the treatment options that are recommended for your condition, no matter what they cost or whether they are covered by our plan. It also includes being told about programs our plan offers to help members manage their medications and use drugs safely.
- **To know about the risks.** You have the right to be told about any risks involved in your care. You must be told in advance if any proposed medical care or treatment is part of a research experiment. You always have the choice to refuse any experimental treatments.
- **The right to say “no.”** You have the right to refuse any recommended treatment. This includes the right to leave a hospital or other medical facility, even if your doctor advises you not to leave. You also have the right to stop taking your medication. Of course, if you refuse treatment or stop taking medication, you accept full responsibility for what happens to your body as a result.
- **To receive an explanation if you are denied coverage for care.** You have the right to receive an explanation from us if a provider has denied care that you believe you should receive. To receive this explanation, you will need to ask us for a coverage decision. Chapter 9 of this booklet tells how to ask the plan for a coverage decision.

You have the right to give instructions about what is to be done if you are not able to make medical decisions for yourself

Sometimes people become unable to make health care decisions for themselves due to accidents or serious illness. You have the right to say what you want to happen if you are in one of these situations. This means that, if you want to, you can:

- Fill out a written form to give **someone the legal authority to make medical decisions for you** if you ever become unable to make decisions for yourself.
- **Give your doctors written instructions** about how you want them to handle your medical care if you become unable to make decisions for yourself.

The legal documents that you can use to give your directions in advance in these situations are called “**advance directives**.” There are different types of advance directives and different names for them. Documents called “**living will**” and “**power of attorney for health care**” are examples of advance directives.

If you want to use an “advance directive” to give your instructions, here is what to do:

- **Get the form.** If you want to have an advance directive, you can get a form from your lawyer, from a social worker, or from some office supply stores. You can sometimes get advance directive forms from organizations that give people information about Medicare.

- **Fill it out and sign it.** Regardless of where you get this form, keep in mind that it is a legal document. You should consider having a lawyer help you prepare it.
- **Give copies to appropriate people.** You should give a copy of the form to your doctor and to the person you name on the form as the one to make decisions for you if you can't. You may want to give copies to close friends or family members as well. Be sure to keep a copy at home.

If you know ahead of time that you are going to be hospitalized, and you have signed an advance directive, **take a copy with you to the hospital.**

- If you are admitted to the hospital, they will ask you whether you have signed an advance directive form and whether you have it with you.
- If you have not signed an advance directive form, the hospital has forms available and will ask if you want to sign one.

Remember, it is your choice whether you want to fill out an advance directive (including whether you want to sign one if you are in the hospital). According to law, no one can deny you care or discriminate against you based on whether or not you have signed an advance directive.

What if your instructions are not followed?

If you have signed an advance directive, and you believe that a doctor or hospital did not follow the instructions in it, you may file a complaint with the state agency that handles advance directives.

Contact information for the state agency that handles advance directives can be found in "Exhibit A" in the back of this document.

Section 1.7	You have the right to make complaints and to ask us to reconsider decisions we have made
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At Humana, a process called Utilization Management (UM) is used to determine whether a service or treatment is covered and appropriate for payment under your benefit plan. Humana does not reward or provide financial incentives to doctors, other individuals or Humana employees for denying coverage or encouraging under use of services. In fact, Humana works with your doctors and other providers to help you get the most appropriate care for your medical condition. If you have questions or concerns related to Utilization Management, staff are available at least eight hours a day during normal business hours. Humana has free language interpreter services available to answer questions related to Utilization Management from non-English speaking members. TTY users should call 1-800-833-3301 or 711.

Humana decides about coverage of new medical procedures and devices on an ongoing basis. This is done by checking peer-reviewed medical literature and consulting with medical experts to see if the new technology is effective and safe. Humana also relies on guidance from the Centers for Medicare & Medicaid Services (CMS), which often makes national coverage decisions for new medical procedures or devices.

If you have any problems or concerns about your covered services or care, Chapter 9 of this booklet tells what you can do. It gives the details about how to deal with all types of problems and complaints.

As explained in Chapter 9, what you need to do to follow up on a problem or concern depends on the situation. You might need to ask our plan to make a coverage decision for you, make an appeal to us to change a coverage decision, or make a complaint. Whatever you do – ask for a coverage decision, make an appeal, or make a complaint – **we are required to treat you fairly.**

You have the right to get a summary of information about the appeals and complaints that other members have filed against our plan in the past. To get this information, please call Customer Care (phone numbers are printed on the back cover of this booklet).

Section 1.8 What can you do if you believe you are being treated unfairly or your rights are not being respected?

If it is about discrimination, call the Office for Civil Rights

If you believe you have been treated unfairly or your rights have not been respected due to your race, disability, religion, sex, health, ethnicity, creed (beliefs), age, or national origin, you should call the Department of Health and Human Services' **Office for Civil Rights** at 1-800-368-1019 or TTY 1-800-537-7697, or call your local Office for Civil Rights.

Is it about something else?

If you believe you have been treated unfairly or your rights have not been respected, and it's not about discrimination, you can get help dealing with the problem you are having:

- You can **call Customer Care** (phone numbers are printed on the back cover of this booklet).
- You can **call the State Health Insurance Assistance Program**. For details about this organization and how to contact it, go to Chapter 2, Section 3.
- Or, **you can call Medicare** at 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.

Section 1.9 How to get more information about your rights

There are several places where you can get more information about your rights:

- You can **call Customer Care** (phone numbers are printed on the back cover of this booklet).
- You can **call the State Health Insurance Assistance Program**. For details about this organization and how to contact it, go to Chapter 2, Section 3.
- You can contact **Medicare**.
 - You can visit the Medicare website to read or download the publication “Your Medicare Rights & Protections.” (The publication is available at: <http://www.medicare.gov/Publications/Pubs/pdf/10112.pdf>.)
 - Or, you can call 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.

SECTION 2 You have some responsibilities as a member of the plan

Section 2.1 What are your responsibilities?

Things you need to do as a member of the plan are listed below. If you have any questions, please call Customer Care (phone numbers are printed on the back cover of this booklet). We're here to help.

- **Get familiar with your covered services and the rules you must follow to get these covered services.** Use this Evidence of Coverage booklet to learn what is covered for you and the rules you need to follow to get your covered services.
 - Chapters 3 and 4 give the details about your medical services, including what is covered, what is not covered, rules to follow, and what you pay.

- Chapters 5 and 6 give the details about your coverage for Part D prescription drugs.
- **If you have any other health insurance coverage or prescription drug coverage in addition to our plan, you are required to tell us.** Please call Customer Care to let us know (phone numbers are printed on the back cover of this booklet).
 - We are required to follow rules set by Medicare to make sure that you are using all of your coverage in combination when you get your covered services from our plan. This is called “**coordination of benefits**” because it involves coordinating the health and drug benefits you get from our plan with any other health and drug benefits available to you. We'll help you coordinate your benefits. (For more information about coordination of benefits, go to Chapter 1, Section 7.)
- **Tell your doctor and other health care providers that you are enrolled in our plan.** Show your plan membership card whenever you get your medical care or Part D prescription drugs.
- **Help your doctors and other providers help you by giving them information, asking questions, and following through on your care.**
 - To help your doctors and other health providers give you the best care, learn as much as you are able to about your health problems and give them the information they need about you and your health. Follow the treatment plans and instructions that you and your doctors agree upon.
 - Make sure your doctors know all of the drugs you are taking, including over-the-counter drugs, vitamins, and supplements.
 - If you have any questions, be sure to ask. Your doctors and other health care providers are supposed to explain things in a way you can understand. If you ask a question and you don't understand the answer you are given, ask again.
- **Be considerate.** We expect all our members to respect the rights of other patients. We also expect you to act in a way that helps the smooth running of your doctor's office, hospitals, and other offices.
- **Pay what you owe.** As a plan member, you are responsible for these payments:
 - In order to be eligible for our plan, you must have Medicare Part A and Medicare Part B. For that reason, some plan members must pay a premium for Medicare Part A and most plan members must pay a premium for Medicare Part B to remain a member of the plan.
 - For most of your medical services or drugs covered by the plan, you must pay your share of the cost when you get the service or drug. This will be a copayment (a fixed amount) or coinsurance (a percentage of the total cost). Chapter 4 tells what you must pay for your medical services. Chapter 6 tells what you must pay for your Part D prescription drugs.
 - If you get any medical services or drugs that are not covered by our plan or by other insurance you may have, you must pay the full cost.
 - > If you disagree with our decision to deny coverage for a service or drug, you can make an appeal. Please see Chapter 9 of this booklet for information about how to make an appeal.
 - If you are required to pay a late enrollment penalty, you must pay the penalty to remain a member of the plan.
 - If you are required to pay the extra amount for Part D because of your yearly income, you must pay the extra amount directly to the government to remain a member of the plan.
- **Tell us if you move.** If you are going to move, it's important to tell us right away. Call Customer Care (phone numbers are printed on the back cover of this booklet).
 - **If you move outside of our plan service area, you cannot remain a member of our plan.** (Chapter 1 tells about our service area.) We can help you figure out whether you are moving outside our service area. If you are leaving our service area, you will have a Special Enrollment Period when you can join any Medicare plan available in your new area. We can let you know if we have a plan in your new area.
 - **If you move within our service area, we still need to know** so we can keep your membership record up to date and know how to contact you.
 - If you move, it is also important to tell Social Security (or the Railroad Retirement Board). You can find phone numbers and contact information for these organizations in Chapter 2.

2014 Evidence of Coverage for Humana Gold Plus H0108-004 (HMO)

Chapter 8: Your rights and responsibilities

- **Call Customer Care for help if you have questions or concerns.** We also welcome any suggestions you may have for improving our plan.
 - Phone numbers and calling hours for Customer Care are printed on the back cover of this booklet.
 - For more information on how to reach us, including our mailing address, please see Chapter 2.

Chapter 9. What to do if you have a problem or complaint (coverage decisions, appeals, complaints)

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BACKGROUND

SECTION 1 Introduction

Section 1.1 What to do if you have a problem or concern

This chapter explains two types of processes for handling problems and concerns:

- For some types of problems, you need to use the **process for coverage decisions and appeals**.
- For other types of problems, you need to use the **process for making complaints**.

Both of these processes have been approved by Medicare. To ensure fairness and prompt handling of your problems, each process has a set of rules, procedures, and deadlines that must be followed by us and by you.

Which one do you use? That depends on the type of problem you are having. The guide in Section 3 will help you identify the right process to use.

Section 1.2 What about the legal terms?

There are technical legal terms for some of the rules, procedures, and types of deadlines explained in this chapter. Many of these terms are unfamiliar to most people and can be hard to understand.

To keep things simple, this chapter explains the legal rules and procedures using simpler words in place of certain legal terms. For example, this chapter generally says "making a complaint" rather than "filing a grievance," "coverage decision" rather than "organization determination" or "coverage determination," and "Independent Review Organization" instead of "Independent Review Entity." It also uses abbreviations as little as possible.

However, it can be helpful – and sometimes quite important – for you to know the correct legal terms for the situation you are in. Knowing which terms to use will help you communicate more clearly and accurately when you are dealing with your problem and get the right help or information for your situation. To help you know which terms to use, we include legal terms when we give the details for handling specific types of situations.

SECTION 2 You can get help from government organizations that are not connected with us

Section 2.1 Where to get more information and personalized assistance

Sometimes it can be confusing to start or follow through the process for dealing with a problem. This can be especially true if you do not feel well or have limited energy. Other times, you may not have the knowledge you need to take the next step.

Get help from an independent government organization

We are always available to help you. But in some situations you may also want help or guidance from someone who is not connected with us. You can always contact your **State Health Insurance Assistance Program (SHIP)**.

This government program has trained counselors in every state. The program is not connected with us or with any insurance company or health plan. The counselors at this program can help you understand which process you should use to handle a problem you are having. They can also answer your questions, give you more information, and offer guidance on what to do.

The services of SHIP counselors are free. You will find phone numbers in "Exhibit A" at the end of this booklet.

You can also get help and information from Medicare

For more information and help in handling a problem, you can also contact Medicare. Here are two ways to get information directly from Medicare:

- You can call 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.
- You can visit the Medicare website (<http://www.medicare.gov>).

SECTION 3 To deal with your problem, which process should you use?

Section 3.1	Should you use the process for coverage decisions and appeals? Or should you use the process for making complaints?
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If you have a problem or concern, you only need to read the parts of this chapter that apply to your situation. The guide that follows will help.

To figure out which part of this chapter will help with your specific problem or concern, **START HERE**

Is your problem or concern about your benefits or coverage?
(This includes problems about whether particular medical care or prescription drugs are covered or not, the way in which they are covered, and problems related to payment for medical care or prescription drugs.)

<p>Yes. My problem is about benefits or coverage.</p> <p>Go on to the next section of this chapter, Section 4, "A guide to the basics of coverage decisions and appeals."</p>	<p>No. My problem is <u>not</u> about benefits or coverage.</p> <p>Skip ahead to Section 10 at the end of this chapter: "How to make a complaint about quality of care, waiting times, customer service or other concerns."</p>
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COVERAGE DECISIONS AND APPEALS

SECTION 4 A guide to the basics of coverage decisions and appeals

Section 4.1 Asking for coverage decisions and making appeals: the big picture

The process for coverage decisions and appeals deals with problems related to your benefits and coverage for medical services and prescription drugs, including problems related to payment. This is the process you use for issues such as whether something is covered or not and the way in which something is covered.

Asking for coverage decisions

A coverage decision is a decision we make about your benefits and coverage or about the amount we will pay for your medical services or drugs. For example, your plan network doctor makes a (favorable) coverage decision for you whenever you receive medical care from him or her or if your network doctor refers you to a medical specialist. You or your doctor can also contact us and ask for a coverage decision if your doctor is unsure whether we will cover a particular medical service or refuses to provide medical care you think that you need. In other words, if you want to know if we will cover a medical service before you receive it, you can ask us to make a coverage decision for you.

We are making a coverage decision for you whenever we decide what is covered for you and how much we pay. In some cases we might decide a service or drug is not covered or is no longer covered by Medicare for you. If you disagree with this coverage decision, you can make an appeal.

Making an appeal

If we make a coverage decision and you are not satisfied with this decision, you can "appeal" the decision. An appeal is a formal way of asking us to review and change a coverage decision we have made.

When you make an appeal, we review the coverage decision we have made to check to see if we were following all of the rules properly. Your appeal is handled by different reviewers than those who made the original unfavorable decision. When we have completed the review, we give you our decision.

If we say no to all or part of your Level 1 Appeal, you can go on to a Level 2 Appeal. The Level 2 Appeal is conducted by an independent organization that is not connected to us. (In some situations, your case will be automatically sent to the independent organization for a Level 2 Appeal. If this happens, we will let you know. In other situations, you will need to ask for a Level 2 Appeal.) If you are not satisfied with the decision at the Level 2 Appeal, you may be able to continue through additional levels of appeal.

Section 4.2 How to get help when you are asking for a coverage decision or making an appeal

Would you like some help? Here are resources you may wish to use if you decide to ask for any kind of coverage decision or appeal a decision:

- You **can call us at Customer Care** (phone numbers are printed on the back cover of this booklet).

- To **get free help from an independent organization** that is not connected with our plan, contact your State Health Insurance Assistance Program (see Section 2 of this chapter).
- **Your doctor can make a request for you.**
 - For medical care, your doctor can request a coverage decision or a Level 1 Appeal on your behalf. If your appeal is denied at Level 1, it will be automatically forwarded to Level 2. To request any appeal after Level 2, your doctor must be appointed as your representative.
 - For Part D prescription drugs, your doctor or other prescriber can request a coverage decision or a Level 1 or 2 Appeal on your behalf. To request any appeal after Level 2, your doctor or other prescriber must be appointed as your representative.
- **You can ask someone to act on your behalf.** If you want to, you can name another person to act for you as your "representative" to ask for a coverage decision or make an appeal.
 - There may be someone who is already legally authorized to act as your representative under state law.
 - If you want a friend, relative, your doctor or other provider, or other person to be your representative, call Customer Care (phone numbers are printed on the back cover of this booklet) and ask for the "Appointment of Representative" form. (The form is also available on Medicare's website at <http://www.cms.hhs.gov/cmsforms/downloads/cms1696.pdf>.) The form gives that person permission to act on your behalf. It must be signed by you and by the person who you would like to act on your behalf. You must give us a copy of the signed form.
- **You also have the right to hire a lawyer to act for you.** You may contact your own lawyer, or get the name of a lawyer from your local bar association or other referral service. There are also groups that will give you free legal services if you qualify. However, **you are not required to hire a lawyer** to ask for any kind of coverage decision or appeal a decision.

Section 4.3 Which section of this chapter gives the details for your situation?

There are four different types of situations that involve coverage decisions and appeals. Since each situation has different rules and deadlines, we give the details for each one in a separate section:

- **Section 5** of this chapter: "Your medical care: How to ask for a coverage decision or make an appeal"
- **Section 6** of this chapter: "Your Part D prescription drugs: How to ask for a coverage decision or make an appeal"
- **Section 7** of this chapter: "How to ask us to cover a longer inpatient hospital stay if you think the doctor is discharging you too soon"
- **Section 8** of this chapter: "How to ask us to keep covering certain medical services if you think your coverage is ending too soon" (Applies to these services only: Home health care, skilled nursing facility care, and Comprehensive Outpatient Rehabilitation Facility (CORF) services)

If you're not sure which section you should be using, please call Customer Care (phone numbers are printed on the back cover of this booklet). You can also get help or information from government organizations such as your State Health Insurance Assistance Program ("Exhibit A" at the end of this booklet has the phone numbers for this program).

SECTION 5 **Your medical care: How to ask for a coverage decision or make an appeal**



Have you read Section 4 of this chapter (A guide to "the basics" of coverage decisions and appeals)?
If not, you may want to read it before you start this section.

Section 5.1	This section tells what to do if you have problems getting coverage for medical care or if you want us to pay you back for our share of the cost of your care
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This section is about your benefits for medical care and services. These benefits are described in Chapter 4 of this booklet: Medical Benefits Chart (what is covered and what you pay). To keep things simple, we generally refer to "medical care coverage" or "medical care" in the rest of this section, instead of repeating "medical care or treatment or services" every time.

This section tells what you can do if you are in any of the five following situations:

1. You are not getting certain medical care you want, and you believe that this care is covered by our plan.
2. Our plan will not approve the medical care your doctor or other medical provider wants to give you, and you believe that this care is covered by the plan.
3. You have received medical care or services that you believe should be covered by the plan, but we have said we will not pay for this care.
4. You have received and paid for medical care or services that you believe should be covered by the plan, and you want to ask our plan to reimburse you for this care.
5. You are being told that coverage for certain medical care you have been getting that we previously approved will be reduced or stopped, and you believe that reducing or stopping this care could harm your health.
 - **NOTE: If the coverage that will be stopped is for hospital care, home health care, skilled nursing facility care, or Comprehensive Outpatient Rehabilitation Facility (CORF) services,** you need to read a separate section of this chapter because special rules apply to these types of care. Here's what to read in those situations:
 - Chapter 9, Section 7: How to ask us to cover a longer inpatient hospital stay if you think the doctor is discharging you too soon.
 - Chapter 9, Section 8: How to ask us to keep covering certain medical services if you think your coverage is ending too soon. This section is about three services only: home health care, skilled nursing facility care, and Comprehensive Outpatient Rehabilitation Facility (CORF) services.
 - For all other situations that involve being told that medical care you have been getting will be stopped, use this section (Section 5) as your guide for what to do.

Which of these situations are you in?

If you are in this situation:	This is what you can do:
Do you want to find out whether we will cover the medical care or services you want?	You can ask us to make a coverage decision for you. Go to the next section of this chapter, Section 5.2 .
Have we already told you that we will not cover or pay for a medical service in the way that you want it to be covered or paid for?	You can make an appeal . (This means you are asking us to reconsider.) Skip ahead to Section 5.3 of this chapter.
Do you want to ask us to pay you back for medical care or services you have already received and paid for?	You can send us the bill. Skip ahead to Section 5.5 of this chapter.

Section 5.2 Step-by-step: How to ask for a coverage decision (how to ask our plan to authorize or provide the medical care coverage you want)

Legal Terms When a coverage decision involves your medical care, it is called an "**organization determination**."

Step 1: You ask our plan to make a coverage decision on the medical care you are requesting. If your health requires a quick response, you should ask us to make a "**fast coverage decision**."

Legal Terms A "fast coverage decision" is called an "**expedited determination**."

How to request coverage for the medical care you want

- Start by calling, writing, or faxing our plan to make your request for us to authorize or provide coverage for the medical care you want. You, your doctor, or your representative can do this.
- For the details on how to contact us, go to Chapter 2, Section 1 and look for the section called, How to contact us when you are asking for a coverage decision about your medical care.

Generally we use the standard deadlines for giving you our decision

When we give you our decision, we will use the "standard" deadlines unless we have agreed to use the "fast" deadlines. **A standard coverage decision means we will give you an answer within 14 days** after we receive your request.

- **However, we can take up to 14 more calendar days** if you ask for more time, or if we need information (such as medical records from out-of-network providers) that may benefit you. If we decide to take extra days to make the decision, we will tell you in writing.

- If you believe we should not take extra days, you can file a "fast complaint" about our decision to take extra days. When you file a fast complaint, we will give you an answer to your complaint within 24 hours. (The process for making a complaint is different from the process for coverage decisions and appeals. For more information about the process for making complaints, including fast complaints, see Section 10 of this chapter.)

If your health requires it, ask us to give you a "fast coverage decision"

- **A fast coverage decision means we will answer within 72 hours.**
 - **However, we can take up to 14 more calendar days** if we find that some information that may benefit you is missing (such as medical records from out-of-network providers), or if you need time to get information to us for the review. If we decide to take extra days, we will tell you in writing.
 - If you believe we should not take extra days, you can file a "fast complaint" about our decision to take extra days. (For more information about the process for making complaints, including fast complaints, see Section 10 of this chapter.) We will call you as soon as we make the decision.
- **To get a fast coverage decision, you must meet two requirements:**
 - You can get a fast coverage decision only if you are asking for coverage for medical care you have not yet received. (You cannot get a fast coverage decision if your request is about payment for medical care you have already received.)
 - You can get a fast coverage decision only if using the standard deadlines could cause serious harm to your health or hurt your ability to function.
- **If your doctor tells us that your health requires a "fast coverage decision," we will automatically agree to give you a fast coverage decision.**
- If you ask for a fast coverage decision on your own, without your doctor's support, we will decide whether your health requires that we give you a fast coverage decision.
 - If we decide that your medical condition does not meet the requirements for a fast coverage decision, we will send you a letter that says so (and we will use the standard deadlines instead).
 - This letter will tell you that if your doctor asks for the fast coverage decision, we will automatically give a fast coverage decision.
 - The letter will also tell how you can file a "fast complaint" about our decision to give you a standard coverage decision instead of the fast coverage decision you requested. (For more information about the process for making complaints, including fast complaints, see Section 10 of this chapter.)

Step 2: We consider your request for medical care coverage and give you our answer.

Deadlines for a "fast" coverage decision

- Generally, for a fast coverage decision, we will give you our answer **within 72 hours**.
 - As explained above, we can take up to 14 more calendar days under certain circumstances. If we decide to take extra days to make the coverage decision, we will tell you in writing.
 - If you believe we should not take extra days, you can file a "fast complaint" about our decision to take extra days. When you file a fast complaint, we will give you an answer to your complaint within 24 hours. (For more information about the process for making complaints, including fast complaints, see Section 10 of this chapter.)
 - If we do not give you our answer within 72 hours (or if there is an extended time period, by the end of that period), you have the right to appeal. Section 5.3 below tells how to make an appeal.
- **If our answer is yes to part or all of what you requested**, we must authorize or provide the medical care coverage we have agreed to provide within 72 hours after we received your request. If we extended the time needed to make our coverage decision, we will provide the coverage by the end of that extended period.

- **If our answer is no to part or all of what you requested**, we will send you a detailed written explanation as to why we said no.

Deadlines for a "standard" coverage decision

- Generally, for a standard coverage decision, we will give you our answer **within 14 days of receiving your request**.
 - We can take up to 14 more calendar days ("an extended time period") under certain circumstances. If we decide to take extra days to make the coverage decision, we will tell you in writing.
 - If you believe we should not take extra days, you can file a "fast complaint" about our decision to take extra days. When you file a fast complaint, we will give you an answer to your complaint within 24 hours. (For more information about the process for making complaints, including fast complaints, see Section 10 of this chapter.)
 - If we do not give you our answer within 14 days (or if there is an extended time period, by the end of that period), you have the right to appeal. Section 5.3 below tells how to make an appeal.
- **If our answer is yes to part or all of what you requested**, we must authorize or provide the coverage we have agreed to provide within 14 days after we received your request. If we extended the time needed to make our coverage decision, we will provide the coverage by the end of that extended period.
- **If our answer is no to part or all of what you requested**, we will send you a written statement that explains why we said no.

Step 3: If we say no to your request for coverage for medical care, you decide if you want to make an appeal.

- If we say no, you have the right to ask us to reconsider – and perhaps change – this decision by making an appeal. Making an appeal means making another try to get the medical care coverage you want.
- If you decide to make an appeal, it means you are going on to Level 1 of the appeals process (see Section 5.3 below).

Section 5.3 Step-by-step: How to make a Level 1 Appeal **(how to ask for a review of a medical care coverage decision made by our plan)**

Legal Terms An appeal to the plan about a medical care coverage decision is called a plan "**reconsideration**."

Step 1: You contact us and make your appeal. If your health requires a quick response, you must ask for a "**fast appeal**."

What to do

- **To start an appeal you, your doctor, or your representative, must contact us.** For details on how to reach us for any purpose related to your appeal, go to Chapter 2, Section 1 and look for the section called, How to contact us when you are making an appeal about your medical care.
- **If you are asking for a standard appeal, make your standard appeal in writing by submitting a request.**
 - If you have someone appealing our decision for you other than your doctor, your appeal must include an Appointment of Representative form authorizing this person to represent you. (To get the form, call Customer Care (phone numbers are printed on the back cover of this booklet) and ask for the

"Appointment of Representative" form. It is also available on Medicare's website at <http://www.cms.hhs.gov/cmsforms/downloads/cms1696.pdf> or on our website at <http://apps.humana.com/marketing/documents.asp?file=639132>.) While we can accept an appeal request without the form, we cannot complete our review until we receive it. If we do not receive the form within 44 days after receiving your appeal request (our deadline for making a decision on your appeal), your appeal request will be sent to the Independent Review Organization for dismissal.

- **If you are asking for a fast appeal, make your appeal in writing or call us** at the phone number shown in Chapter 2, Section 1 (How to contact us when you are making an appeal about your medical care).
- **You must make your appeal request within 60 calendar days** from the date on the written notice we sent to tell you our answer to your request for a coverage decision. If you miss this deadline and have a good reason for missing it, we may give you more time to make your appeal. Examples of good cause for missing the deadline may include if you had a serious illness that prevented you from contacting us or if we provided you with incorrect or incomplete information about the deadline for requesting an appeal.
- **You can ask for a copy of the information regarding your medical decision and add more information to support your appeal.**
 - You have the right to ask us for a copy of the information regarding your appeal. We are allowed to charge a fee for copying and sending this information to you.
 - If you wish, you and your doctor may give us additional information to support your appeal.

If your health requires it, ask for a "fast appeal" (you can make a request by calling us)

Legal Terms	A "fast appeal" is also called an "expedited reconsideration."
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- If you are appealing a decision we made about coverage for care you have not yet received, you and/or your doctor will need to decide if you need a "fast appeal."
- The requirements and procedures for getting a "fast appeal" are the same as those for getting a "fast coverage decision." To ask for a fast appeal, follow the instructions for asking for a fast coverage decision. (These instructions are given earlier in this section.)
- If your doctor tells us that your health requires a "fast appeal," we will give you a fast appeal.

Step 2: We consider your appeal and we give you our answer.

- When our plan is reviewing your appeal, we take another careful look at all of the information about your request for coverage of medical care. We check to see if we were following all the rules when we said no to your request.
- We will gather more information if we need it. We may contact you or your doctor to get more information.

Deadlines for a "fast" appeal

- When we are using the fast deadlines, we must give you our answer **within 72 hours after we receive your appeal**. We will give you our answer sooner if your health requires us to do so.
 - However, if you ask for more time, or if we need to gather more information that may benefit you, we **can take up to 14 more calendar days**. If we decide to take extra days to make the decision, we will tell you in writing.
 - If we do not give you an answer within 72 hours (or by the end of the extended time period if we took extra days), we are required to automatically send your request on to Level 2 of the appeals process, where it will be reviewed by an independent organization. Later in this section, we tell you about this organization and explain what happens at Level 2 of the appeals process.
- **If our answer is yes to part or all of what you requested**, we must authorize or provide the coverage we have agreed to provide within 72 hours after we receive your appeal.

- **If our answer is no to part or all of what you requested**, we will send you a written denial notice informing you that we have automatically sent your appeal to the Independent Review Organization for a Level 2 Appeal.

Deadlines for a "standard" appeal

- If we are using the standard deadlines, we must give you our answer **within 30 calendar days** after we receive your appeal if your appeal is about coverage for services you have not yet received. We will give you our decision sooner if your health condition requires us to.
 - However, if you ask for more time, or if we need to gather more information that may benefit you, **we can take up to 14 more calendar days**.
 - If you believe we should not take extra days, you can file a "fast complaint" about our decision to take extra days. When you file a fast complaint, we will give you an answer to your complaint within 24 hours. (For more information about the process for making complaints, including fast complaints, see Section 10 of this chapter.)
 - If we do not give you an answer by the deadline above (or by the end of the extended time period if we took extra days), we are required to send your request on to Level 2 of the appeals process, where it will be reviewed by an independent outside organization. Later in this section, we talk about this review organization and explain what happens at Level 2 of the appeals process.
- **If our answer is yes to part or all of what you requested**, we must authorize or provide the coverage we have agreed to provide within 30 days after we receive your appeal.
- **If our answer is no to part or all of what you requested**, we will send you a written denial notice informing you that we have automatically sent your appeal to the Independent Review Organization for a Level 2 Appeal.

Step 3: If our plan says no to part or all of your appeal, your case will automatically be sent on to the next level of the appeals process.

- To make sure we were following all the rules when we said no to your appeal, **we are required to send your appeal to the "Independent Review Organization."** When we do this, it means that your appeal is going on to the next level of the appeals process, which is Level 2.

Section 5.4 Step-by-step: How a Level 2 Appeal is done

If we say no to your Level 1 Appeal, your case will automatically be sent on to the next level of the appeals process. During the Level 2 Appeal, the **Independent Review Organization** reviews our decision for your first appeal. This organization decides whether the decision we made should be changed.

Legal Terms	The formal name for the "Independent Review Organization" is the " Independent Review Entity ." It is sometimes called the " IRE ."
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Step 1: The Independent Review Organization reviews your appeal.

- **The Independent Review Organization is an independent organization that is hired by Medicare.** This organization is not connected with us and it is not a government agency. This organization is a company chosen by Medicare to handle the job of being the Independent Review Organization. Medicare oversees its work.
- We will send the information about your appeal to this organization. This information is called your "case file." **You have the right to ask us for a copy of your case file.** We are allowed to charge you a fee for copying and sending this information to you.

- You have a right to give the Independent Review Organization additional information to support your appeal.
- Reviewers at the Independent Review Organization will take a careful look at all of the information related to your appeal.

If you had a "fast" appeal at Level 1, you will also have a **"fast" appeal** at Level 2

- If you had a fast appeal to our plan at Level 1, you will automatically receive a fast appeal at Level 2. The review organization must give you an answer to your Level 2 Appeal **within 72 hours** of when it receives your appeal.
- However, if the Independent Review Organization needs to gather more information that may benefit you, **it can take up to 14 more calendar days.**

If you had a "standard" appeal at Level 1, you will also have a **"standard" appeal** at Level 2

- If you had a standard appeal to our plan at Level 1, you will automatically receive a standard appeal at Level 2. The review organization must give you an answer to your Level 2 Appeal **within 30 calendar days** of when it receives your appeal.
- However, if the Independent Review Organization needs to gather more information that may benefit you, **it can take up to 14 more calendar days.**

Step 2: The Independent Review Organization gives you their answer.

The Independent Review Organization will tell you its decision in writing and explain the reasons for it.

- **If the review organization says yes to part or all of what you requested**, we must authorize the medical care coverage within 72 hours or provide the service within 14 calendar days after we receive the decision from the review organization.
- **If this organization says no to part or all of your appeal**, it means they agree with us that your request (or part of your request) for coverage for medical care should not be approved. (This is called "upholding the decision." It is also called "turning down your appeal.")
 - There is certain dollar value that must be in dispute to continue with the appeals process. For example, to continue and make another appeal at Level 3, the dollar value of the medical care coverage you are requesting must meet a certain minimum. If the dollar value of the coverage you are requesting is too low, you cannot make another appeal, which means that the decision at Level 2 is final. The written notice you get from the Independent Review Organization will tell you how to find out the dollar amount to continue the appeals process.

Step 3: If your case meets the requirements, you choose whether you want to take your appeal further.

- There are three additional levels in the appeals process after Level 2 (for a total of five levels of appeal).
- If your Level 2 Appeal is turned down and you meet the requirements to continue with the appeals process, you must decide whether you want to go on to Level 3 and make a third appeal. The details on how to do this are in the written notice you got after your Level 2 Appeal.
- The Level 3 Appeal is handled by an administrative law judge. Section 9 in this chapter tells more about Levels 3, 4, and 5 of the appeals process.

Section 5.5	What if you are asking us to pay you for our share of a bill you have received for medical care?
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If you want to ask us for payment for medical care, start by reading Chapter 7 of this booklet: Asking us to pay our share of a bill you have received for covered medical services or drugs. Chapter 7 describes the situations in which

you may need to ask for reimbursement or to pay a bill you have received from a provider. It also tells how to send us the paperwork that asks us for payment.

Asking for reimbursement is asking for a coverage decision from us

If you send us the paperwork that asks for reimbursement, you are asking us to make a coverage decision (for more information about coverage decisions, see Section 4.1 of this chapter). To make this coverage decision, we will check to see if the medical care you paid for is a covered service (see Chapter 4: Medical Benefits Chart (what is covered and what you pay)). We will also check to see if you followed all the rules for using your coverage for medical care (these rules are given in Chapter 3 of this booklet: Using the plan's coverage for your medical services).

We will say yes or no to your request

- If the medical care you paid for is covered and you followed all the rules, we will send you the payment for our share of the cost of your medical care within 60 calendar days after we receive your request. Or, if you haven't paid for the services, we will send the payment directly to the provider. (When we send the payment, it's the same as saying yes to your request for a coverage decision.)
- If the medical care is not covered, or you did not follow all the rules, we will not send payment. Instead, we will send you a letter that says we will not pay for the services and the reasons why in detail. (When we turn down your request for payment, it's the same as saying no to your request for a coverage decision.)

What if you ask for payment and we say that we will not pay?

If you do not agree with our decision to turn you down, **you can make an appeal**. If you make an appeal, it means you are asking us to change the coverage decision we made when we turned down your request for payment.

To make this appeal, follow the process for appeals that we describe in part 5.3 of this section. Go to this part for step-by-step instructions. When you are following these instructions, please note:

- If you make an appeal for reimbursement, we must give you our answer within 60 calendar days after we receive your appeal. (If you are asking us to pay you back for medical care you have already received and paid for yourself, you are not allowed to ask for a fast appeal.)
- If the Independent Review Organization reverses our decision to deny payment, we must send the payment you have requested to you or to the provider within 30 calendar days. If the answer to your appeal is yes at any stage of the appeals process after Level 2, we must send the payment you requested to you or to the provider within 60 calendar days.

SECTION 6 Your Part D prescription drugs: How to ask for a coverage decision or make an appeal



Have you read Section 4 of this chapter (A guide to “the basics” of coverage decisions and appeals)? If not, you may want to read it before you start this section.

Section 6.1	This section tells you what to do if you have problems getting a Part D drug or you want us to pay you back for a Part D drug
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Your benefits as a member of our plan include coverage for many prescription drugs. Please refer to our plan's Prescription Drug Guide (Formulary). To be covered, the drug must be used for a medically accepted indication. (A "medically accepted indication" is a use of the drug that is either approved by the Food and Drug Administration or supported by certain reference books. See Chapter 5, Section 3 for more information about a medically accepted indication.)

- **This section is about your Part D drugs only.** To keep things simple, we generally say "drug" in the rest of this section, instead of repeating "covered outpatient prescription drug" or "Part D drug" every time.
- For details about what we mean by Part D drugs, the Prescription Drug Guide (Formulary), rules and restrictions on coverage, and cost information, see Chapter 5 (Using our plan's coverage for your Part D prescription drugs) and Chapter 6 (What you pay for your Part D prescription drugs).

Part D coverage decisions and appeals

As discussed in Section 4 of this chapter, a coverage decision is a decision we make about your benefits and coverage or about the amount we will pay for your drugs.

Legal Terms	An initial coverage decision about your Part D drugs is called a "coverage determination."
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Here are examples of coverage decisions you ask us to make about your Part D drugs:

- You ask us to make an exception, including:
 - Asking us to cover a Part D drug that is not in the plan's Prescription Drug Guide (Formulary)
 - Asking us to waive a restriction on the plan's coverage for a drug (such as limits on the amount of the drug you can get)
 - Asking to pay a lower cost-sharing amount for a covered non-preferred drug
- You ask us whether a drug is covered for you and whether you satisfy any applicable coverage rules. (For example, when your drug is in the plan's Prescription Drug Guide (Formulary) but we require you to get approval from us before we will cover it for you.)
 - Please note: If your pharmacy tells you that your prescription cannot be filled as written, you will get a written notice explaining how to contact us to ask for a coverage decision.
- You ask us to pay for a prescription drug you already bought. This is a request for a coverage decision about payment.

If you disagree with a coverage decision we have made, you can appeal our decision.

This section tells you both how to ask for coverage decisions and how to request an appeal. Use the chart below to help you determine which part has information for your situation:

Which of these situations are you in?			
Do you need a drug that isn't in our Drug Guide or need us to waive a rule or restriction on a drug we cover?	Do you want us to cover a drug in our Drug Guide and you believe you meet any plan rules or restrictions (such as getting approval in advance) for the drug you need?	Do you want to ask us to pay you back for a drug you have already received and paid for?	Have we already told you that we will not cover or pay for a drug in the way that you want it to be covered or paid for?
You can ask us to make an exception. (This is a type of coverage decision.)	You can ask us for a coverage decision.	You can ask us to pay you back. (This is a type of coverage decision.)	You can make an appeal. (This means you are asking us to reconsider.)
Start with Section 6.2 of this chapter.	Skip ahead to Section 6.4 of this chapter.	Skip ahead to Section 6.4 of this chapter.	Skip ahead to Section 6.5 of this chapter

Section 6.2 What is an exception?

If a drug is not covered in the way you would like it to be covered, you can ask us to make an "exception." An exception is a type of coverage decision. Similar to other types of coverage decisions, if we turn down your request for an exception, you can appeal our decision.

When you ask for an exception, your doctor or other prescriber will need to explain the medical reasons why you need the exception approved. We will then consider your request. Here are three examples of exceptions that you or your doctor or other prescriber can ask us to make:

1. Covering a Part D drug for you that is not in our plan's Prescription Drug Guide (Formulary). (We call it the "Drug Guide" for short.)

Legal Terms Asking for coverage of a drug that is not in the Drug Guide is sometimes called asking for a **"formulary exception."**

- If we agree to make an exception and cover a drug that is not in the Drug Guide, you will need to pay the cost-sharing amount that applies to Cost-Sharing Tier 4 – Non-Preferred Brand Drugs. You cannot ask for an exception to the copayment or coinsurance amount we require you to pay for the drug.

2. Removing a restriction on our coverage for a covered drug. There are extra rules or restrictions that apply to certain drugs in our Prescription Drug Guide (Formulary) (for more information, go to Chapter 5 and look for Section 4).

Legal Terms	Asking for removal of a restriction on coverage for a drug is sometimes called asking for a “formulary exception.”
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- The extra rules and restrictions on coverage for certain drugs include:
 - Being required to use the generic version** of a drug instead of the brand-name drug.
 - Getting plan approval in advance** before we will agree to cover the drug for you. (This is sometimes called "prior authorization.")
 - Being required to try a different drug first** before we will agree to cover the drug you are asking for. (This is sometimes called "step therapy.")
 - Quantity limits.** For some drugs, there are restrictions on the amount of the drug you can have.
- If we agree to make an exception and waive a restriction for you, you can ask for an exception to the copayment or coinsurance amount we require you to pay for the drug.

3. Changing coverage of a drug to a lower cost-sharing tier. Every drug in our Drug Guide is in one of five cost-sharing tiers. In general, the lower the cost-sharing tier number, the less you will pay as your share of the cost of the drug.

Legal Terms	Asking to pay a lower preferred price for a covered non-preferred drug is sometimes called asking for a “tiering exception.”
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- If your drug is in Cost-Sharing Tier 4 – Non-Preferred Brand Drugs you can ask us to cover it at the cost-sharing amount that applies to Tier 3 – Preferred Brand Drugs. This would lower your share of the cost for the drug.
- If your generic drug is in the Cost-Sharing Tier 2 – Non-Preferred Generics you can ask us to cover it at the cost-sharing amount that applies to Tier 1 – Preferred Generic Drugs. This would lower your share of the cost for the drug.
- You cannot ask us to change the cost-sharing tier for any drug in Tier 5 – Specialty Drugs.

Section 6.3 Important things to know about asking for exceptions

Your doctor must tell us the medical reasons

Your doctor or other prescriber must give us a statement that explains the medical reasons for requesting an exception. For a faster decision, include this medical information from your doctor or other prescriber when you ask for the exception.

Typically, our Drug Guide includes more than one drug for treating a particular condition. These different possibilities are called "alternative" drugs. If an alternative drug would be just as effective as the drug you are requesting and would not cause more side effects or other health problems, we will generally not approve your request for an exception.

We can say yes or no to your request

- If we approve your request for an exception, our approval usually is valid until the end of the plan year. This is true as long as your doctor continues to prescribe the drug for you and that drug continues to be safe and effective for treating your condition.
- If we say no to your request for an exception, you can ask for a review of our decision by making an appeal. Section 6.5 tells how to make an appeal if we say no.

The next section tells you how to ask for a coverage decision, including an exception.

Section 6.4 Step-by-step: How to ask for a coverage decision, including an exception

Step 1: You ask us to make a coverage decision about the drug(s) or payment you need. If your health requires a quick response, you must ask us to make a "fast coverage decision." You cannot ask for a fast coverage decision if you are asking us to pay you back for a drug you already bought.

What to do

- **Request the type of coverage decision you want.** Start by calling, writing, or faxing us to make your request. You, your representative, or your doctor (or other prescriber) can do this. You can also access the coverage decision process through our website. For the details, go to Chapter 2, Section 1 and look for the section called, How to contact us when you are asking for a coverage decision about your Part D prescription drugs. Or if you are asking us to pay you back for a drug, go to the section called, Where to send a request asking us to pay for our share of the cost for medical care or a drug you have received.
- **You or your doctor or someone else who is acting on your behalf** can ask for a coverage decision. Section 4 of this chapter tells how you can give written permission to someone else to act as your representative. You can also have a lawyer act on your behalf.
- **If you want to ask us to pay you back for a drug,** start by reading Chapter 7 of this booklet: Asking us to pay our share of a bill you have received for covered medical services or drugs. Chapter 7 describes the situations in which you may need to ask for reimbursement. It also tells how to send us the paperwork that asks us to pay you back for our share of the cost of a drug you have paid for.
- **If you are requesting an exception, provide the "supporting statement."** Your doctor or other prescriber must give us the medical reasons for the drug exception you are requesting. (We call this the "supporting statement.") Your doctor or other prescriber can fax or mail the statement to us. Or your doctor or other prescriber can tell us on the phone and follow up by faxing or mailing a written statement if necessary. See Sections 6.2 and 6.3 for more information about exception requests.
- **We must accept any written request,** including a request submitted on the CMS Model Coverage Determination Request Form, which is available on our website.
- **To submit a coverage determination request online,** please go to:
http://www.humana.com/medicare/medicare_prescription_drugs/medicare_drug_tools/determination.aspx. Fill out the Coverage Determination Request Form. You'll need to send us supporting documentation from the prescribing doctor to show medical need. Your information will be sent to us securely.

If your health requires it, ask us to give you a "fast coverage decision"

Legal Terms	A "fast coverage decision" is called an "expedited coverage determination."
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- When we give you our decision, we will use the "standard" deadlines unless we have agreed to use the "fast" deadlines. A standard coverage decision means we will give you an answer within 72 hours after we receive your doctor's statement. A fast coverage decision means we will answer within 24 hours.
- **To get a fast coverage decision, you must meet two requirements:**
 - You can get a fast coverage decision only if you are asking for a drug you have not yet received. (You cannot get a fast coverage decision if you are asking us to pay you back for a drug you have already bought.)
 - You can get a fast coverage decision only if using the standard deadlines could cause serious harm to your health or hurt your ability to function.
- **If your doctor or other prescriber tells us that your health requires a "fast coverage decision," we will automatically agree to give you a fast coverage decision.**
- If you ask for a fast coverage decision on your own (without your doctor's or other prescriber's support), we will decide whether your health requires that we give you a fast coverage decision.
 - If we decide that your medical condition does not meet the requirements for a fast coverage decision, we will send you a letter that says so (and we will use the standard deadlines instead).
 - This letter will tell you that if your doctor or other prescriber asks for the fast coverage decision, we will automatically give a fast coverage decision.
 - The letter will also tell how you can file a complaint about our decision to give you a standard coverage decision instead of the fast coverage decision you requested. It tells how to file a "fast" complaint, which means you would get our answer to your complaint within 24 hours. (The process for making a complaint is different from the process for coverage decisions and appeals. For more information about the process for making complaints, see Section 10 of this chapter.)

Step 2: We consider your request and we give you our answer.

Deadlines for a "fast" coverage decision

- If we are using the fast deadlines, we must give you our answer **within 24 hours**.
 - Generally, this means within 24 hours after we receive your request. If you are requesting an exception, we will give you our answer within 24 hours after we receive your doctor's statement supporting your request. We will give you our answer sooner if your health requires us to.
 - If we do not meet this deadline, we are required to send your request on to Level 2 of the appeals process, where it will be reviewed by an independent outside organization. Later in this section, we talk about this review organization and explain what happens at Appeal Level 2.
- **If our answer is yes to part or all of what you requested**, we must provide the coverage we have agreed to provide within 24 hours after we receive your request or doctor's statement supporting your request.
- **If our answer is no to part or all of what you requested**, we will send you a written statement that explains why we said no. We will also tell you how to appeal.

Deadlines for a "standard" coverage decision about a drug you have not yet received

- If we are using the standard deadlines, we must give you our answer **within 72 hours**.
 - Generally, this means within 72 hours after we receive your request. If you are requesting an exception, we will give you our answer within 72 hours after we receive your doctor's statement supporting your request. We will give you our answer sooner if your health requires us to.

- If we do not meet this deadline, we are required to send your request on to Level 2 of the appeals process, where it will be reviewed by an independent organization. Later in this section, we talk about this review organization and explain what happens at Appeal Level 2.
- **If our answer is yes to part or all of what you requested –**
 - If we approve your request for coverage, we must **provide the coverage** we have agreed to provide **within 72 hours** after we receive your request or doctor's statement supporting your request.
- **If our answer is no to part or all of what you requested,** we will send you a written statement that explains why we said no. We will also tell you how to appeal.

Deadlines for a "standard" coverage decision about payment for a drug you have already bought

- We must give you our answer **within 14 calendar days** after we receive your request.
 - If we do not meet this deadline, we are required to send your request on to Level 2 of the appeals process, where it will be reviewed by an independent organization. Later in this section, we talk about this review organization and explain what happens at Appeal Level 2.
- **If our answer is yes to part or all of what you requested,** we are also required to make payment to you within 14 calendar days after we receive your request.
- **If our answer is no to part or all of what you requested,** we will send you a written statement that explains why we said no. We will also tell you how to appeal.

Step 3: If we say no to your coverage request, you decide if you want to make an appeal.

- If we say no, you have the right to request an appeal. Requesting an appeal means asking us to reconsider – and possibly change – the decision we made.

Section 6.5	Step-by-step: How to make a Level 1 Appeal (how to ask for a review of a coverage decision made by our plan)
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Legal Terms	An appeal to the plan about a Part D drug coverage decision is called a plan “redetermination.”
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Step 1: You contact us and make your Level 1 Appeal. If your health requires a quick response, you must ask for a **"fast appeal."**

What to do

- **To start your appeal, you (or your representative or your doctor or other prescriber) must contact us.**
 - For details on how to reach us by phone, fax, or mail, or on our website for any purpose related to your appeal, go to Chapter 2, Section 1, and look for the section called, How to contact us when you are making an appeal about your Part D prescription drugs.
- **If you are asking for a standard appeal, make your appeal by submitting a written request.**
- **If you are asking for a fast appeal, you may make your appeal in writing or you may call us at the phone number shown in Chapter 2, Section 1** (How to contact us when you are making an appeal about your part D prescription drugs).
- **We must accept any written request,** including a request submitted on the CMS Model Coverage Determination Request Form, which is available on our web site.
- **You must make your appeal request within 60 calendar days** from the date on the written notice we sent to tell you our answer to your request for a coverage decision. If you miss this deadline and have a good reason for missing it, we may give you more time to make your appeal. Examples of good cause for

missing the deadline may include if you had a serious illness that prevented you from contacting us or if we provided you with incorrect or incomplete information about the deadline for requesting an appeal.

- **You can ask for a copy of the information in your appeal and add more information.**
 - You have the right to ask us for a copy of the information regarding your appeal. We are allowed to charge a fee for copying and sending this information to you.
 - If you wish, you and your doctor or other prescriber may give us additional information to support your appeal.

If your health requires it, ask for a "fast appeal"

Legal Terms	A "fast appeal" is also called an "expedited redetermination."
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- If you are appealing a decision we made about a drug you have not yet received, you and your doctor or other prescriber will need to decide if you need a "fast appeal."
- The requirements for getting a "fast appeal" are the same as those for getting a "fast coverage decision" in Section 6.4 of this chapter.

Step 2: We consider your appeal and we give you our answer.

- When we are reviewing your appeal, we take another careful look at all of the information about your coverage request. We check to see if we were following all the rules when we said no to your request. We may contact you or your doctor or other prescriber to get more information.

Deadlines for a "fast" appeal

- If we are using the fast deadlines, we must give you our answer **within 72 hours after we receive your appeal**. We will give you our answer sooner if your health requires it.
 - If we do not give you an answer within 72 hours, we are required to send your request on to Level 2 of the appeals process, where it will be reviewed by an Independent Review Organization. Later in this section, we talk about this review organization and explain what happens at Level 2 of the appeals process.
- **If our answer is yes to part or all of what you requested**, we must provide the coverage we have agreed to provide within 72 hours after we receive your appeal.
- **If our answer is no to part or all of what you requested**, we will send you a written statement that explains why we said no and how to appeal our decision.

Deadlines for a "standard" appeal

- If we are using the standard deadlines, we must give you our answer **within 7 calendar days** after we receive your appeal. We will give you our decision sooner if you have not received the drug yet and your health condition requires us to do so. If you believe your health requires it, you should ask for "fast" appeal.
 - If we do not give you a decision within 7 calendar days, we are required to send your request on to Level 2 of the appeals process, where it will be reviewed by an Independent Review Organization. Later in this section, we tell about this review organization and explain what happens at Level 2 of the appeals process.
- **If our answer is yes to part or all of what you requested –**
 - If we approve a request for coverage, we must **provide the coverage** we have agreed to provide as quickly as your health requires, but **no later than 7 calendar days** after we receive your appeal.
 - If we approve a request to pay you back for a drug you already bought, we are required to **send payment to you within 30 calendar days** after we receive your appeal request.

- **If our answer is no to part or all of what you requested**, we will send you a written statement that explains why we said no and how to appeal our decision.

Step 3: If we say no to your appeal, you decide if you want to continue with the appeals process and make another appeal.

- If we say no to your appeal, you then choose whether to accept this decision or continue by making another appeal.
- If you decide to make another appeal, it means your appeal is going on to Level 2 of the appeals process (see below).

Section 6.6 Step-by-step: How to make a Level 2 Appeal

If we say no to your appeal, you then choose whether to accept this decision or continue by making another appeal. If you decide to go on to a Level 2 Appeal, the **Independent Review Organization** reviews the decision we made when we said no to your first appeal. This organization decides whether the decision we made should be changed.

Legal Terms The formal name for the “Independent Review Organization” is the **“Independent Review Entity.”** It is sometimes called the **“IRE.”**

Step 1: To make a Level 2 Appeal, you (or your representative or your doctor or other prescriber) must contact the Independent Review Organization and ask for a review of your case.

- If we say no to your Level 1 Appeal, the written notice we send you will include **instructions on how to make a Level 2 Appeal** with the Independent Review Organization. These instructions will tell who can make this Level 2 Appeal, what deadlines you must follow, and how to reach the review organization.
- When you make an appeal to the Independent Review Organization, we will send the information we have about your appeal to this organization. This information is called your “case file.” **You have the right to ask us for a copy of your case file.** We are allowed to charge you a fee for copying and sending this information to you.
- You have a right to give the Independent Review Organization additional information to support your appeal.

Step 2: The Independent Review Organization does a review of your appeal and gives you an answer.

- **The Independent Review Organization is an independent organization that is hired by Medicare.** This organization is not connected with us and it is not a government agency. This organization is a company chosen by Medicare to review our decisions about your Part D benefits with us.
- Reviewers at the Independent Review Organization will take a careful look at all of the information related to your appeal. The organization will tell you its decision in writing and explain the reasons for it.

Deadlines for “fast” appeal at Level 2

- If your health requires it, ask the Independent Review Organization for a “fast appeal.”
- If the review organization agrees to give you a “fast appeal,” the review organization must give you an answer to your Level 2 Appeal **within 72 hours** after it receives your appeal request.
- **If the Independent Review Organization says yes to part or all of what you requested**, we must provide the drug coverage that was approved by the review organization **within 24 hours** after we receive the decision from the review organization.

Deadlines for "**standard**" appeal at Level 2

- If you have a standard appeal at Level 2, the review organization must give you an answer to your Level 2 Appeal **within 7 calendar days** after it receives your appeal.
- **If the Independent Review Organization says yes to part or all of what you requested –**
 - If the Independent Review Organization approves a request for coverage, we must **provide the drug coverage** that was approved by the review organization **within 72 hours** after we receive the decision from the review organization.
 - If the Independent Review Organization approves a request to pay you back for a drug you already bought, we are required to **send payment to you within 30 calendar days** after we receive the decision from the review organization.

What if the review organization says no to your appeal?

If this organization says no to your appeal, it means the organization agrees with our decision not to approve your request. (This is called "upholding the decision." It is also called "turning down your appeal.")

To continue and make another appeal at Level 3, the dollar value of the drug coverage you are requesting must meet a minimum amount. If the dollar value of the coverage you are requesting is too low, you cannot make another appeal and the decision at Level 2 is final. The notice you get from the Independent Review Organization will tell you the dollar value that must be in dispute to continue with the appeals process.

Step 3: If the dollar value of the coverage you are requesting meets the requirement, you choose whether you want to take your appeal further.

- There are three additional levels in the appeals process after Level 2 (for a total of five levels of appeal).
- If your Level 2 Appeal is turned down and you meet the requirements to continue with the appeals process, you must decide whether you want to go on to Level 3 and make a third appeal. If you decide to make a third appeal, the details on how to do this are in the written notice you got after your second appeal.
- The Level 3 Appeal is handled by an administrative law judge. Section 9 in this chapter tells more about Levels 3, 4, and 5 of the appeals process.

SECTION 7 How to ask us to cover a longer inpatient hospital stay if you think the doctor is discharging you too soon

When you are admitted to a hospital, you have the right to get all of your covered hospital services that are necessary to diagnose and treat your illness or injury. For more information about our coverage for your hospital care, including any limitations on this coverage, see Chapter 4 of this booklet: Medical Benefits Chart (what is covered and what you pay).

During your hospital stay, your doctor and the hospital staff will be working with you to prepare for the day when you will leave the hospital. They will also help arrange for care you may need after you leave.

- The day you leave the hospital is called your "**discharge date.**" Our plan's coverage of your hospital stay ends on this date.
- When your discharge date has been decided, your doctor or the hospital staff will let you know.
- If you think you are being asked to leave the hospital too soon, you can ask for a longer hospital stay and your request will be considered. This section tells you how to ask.

Section 7.1 During your inpatient hospital stay, you will get a written notice from Medicare that tells about your rights

During your hospital stay, you will be given a written notice called An Important Message from Medicare about Your Rights. Everyone with Medicare gets a copy of this notice whenever they are admitted to a hospital. Someone at the hospital (for example, a caseworker or nurse) must give it to you within two days after you are admitted. If you do not get the notice, ask any hospital employee for it. If you need help, please call Customer Care (phone numbers are printed on the back cover of this booklet). You can also call 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.

- 1. Read this notice carefully and ask questions if you don't understand it.** It tells you about your rights as a hospital patient, including:
 - Your right to receive Medicare-covered services during and after your hospital stay, as ordered by your doctor. This includes the right to know what these services are, who will pay for them, and where you can get them.
 - Your right to be involved in any decisions about your hospital stay, and know who will pay for it.
 - Where to report any concerns you have about quality of your hospital care.
 - Your right to appeal your discharge decision if you think you are being discharged from the hospital too soon.

Legal Terms	The written notice from Medicare tells you how you can “request an immediate review.” Requesting an immediate review is a formal, legal way to ask for a delay in your discharge date so that we will cover your hospital care for a longer time. (Section 7.2 below tells you how you can request an immediate review.)
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- 2. You must sign the written notice to show that you received it and understand your rights.**
 - You or someone who is acting on your behalf must sign the notice. (Section 4 of this chapter tells how you can give written permission to someone else to act as your representative.)
 - Signing the notice shows only that you have received the information about your rights. The notice does not give your discharge date (your doctor or hospital staff will tell you your discharge date). Signing the notice **does not mean** you are agreeing on a discharge date.
- 3. Keep your copy** of the signed notice so you will have the information about making an appeal (or reporting a concern about quality of care) handy if you need it.
 - If you sign the notice more than two days before the day you leave the hospital, you will get another copy before you are scheduled to be discharged.
 - To look at a copy of this notice in advance, you can call Customer Care (phone numbers are printed on the back cover of this booklet) or 1-800 MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048. You can also see it online at http://www.cms.gov/BNI/12_HospitalDischargeAppealNotices.asp.

Section 7.2 Step-by-step: How to make a Level 1 Appeal to change your hospital discharge date

If you want to ask for your inpatient hospital services to be covered by us for a longer time, you will need to use the appeals process to make this request. Before you start, understand what you need to do and what the deadlines are.

- **Follow the process.** Each step in the first two levels of the appeals process is explained below.
- **Meet the deadlines.** The deadlines are important. Be sure that you understand and follow the deadlines that apply to things you must do.
- **Ask for help if you need it.** If you have questions or need help at any time, please call Customer Care (phone numbers are printed on the back cover of this booklet). Or call your State Health Insurance Assistance Program, a government organization that provides personalized assistance (see Section 2 of this chapter).

During a Level 1 Appeal, the Quality Improvement Organization reviews your appeal. It checks to see if your planned discharge date is medically appropriate for you.

Step 1: Contact the Quality Improvement Organization in your state and ask for a “fast review” of your hospital discharge. You must act quickly.

Legal Terms

A “fast review” is also called an **“immediate review.”**

What is the Quality Improvement Organization?

- This organization is a group of doctors and other health care professionals who are paid by the federal government. These experts are not part of our plan. This organization is paid by Medicare to check on and help improve the quality of care for people with Medicare. This includes reviewing hospital discharge dates for people with Medicare.

How can you contact this organization?

- The written notice you received (An Important Message from Medicare About Your Rights) tells you how to reach this organization. (Or find the name, address, and phone number of the Quality Improvement Organization for your state in Chapter 2, Section 4, of this booklet.)

Act quickly:

- To make your appeal, you must contact the Quality Improvement Organization before you leave the hospital and **no later than your planned discharge date**. (Your “planned discharge date” is the date that has been set for you to leave the hospital.)
 - If you meet this deadline, you are allowed to stay in the hospital after your discharge date without paying for it while you wait to get the decision on your appeal from the Quality Improvement Organization.
 - If you do not meet this deadline, and you decide to stay in the hospital after your planned discharge date, you may have to pay all of the costs for hospital care you receive after your planned discharge date.

- If you miss the deadline for contacting the Quality Improvement Organization about your appeal, you can make your appeal directly to our plan instead. For details about this other way to make your appeal, see Section 7.4.

Ask for a “fast review”:

- You must ask the Quality Improvement Organization for a **“fast review”** of your discharge. Asking for a “fast review” means you are asking for the organization to use the “fast” deadlines for an appeal instead of using the standard deadlines.

Legal Terms	A “fast review” is also called an “immediate review” or an “expedited review.”
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Step 2: The Quality Improvement Organization conducts an independent review of your case.

What happens during this review?

- Health professionals at the Quality Improvement Organization (we will call them “the reviewers” for short) will ask you (or your representative) why you believe coverage for the services should continue. You don't have to prepare anything in writing, but you may do so if you wish.
- The reviewers will also look at your medical information, talk with your doctor, and review information that the hospital and we have given to them.
- By noon of the day after the reviewers informed our plan of your appeal, you will also get a written notice that gives your planned discharge date and explains in detail the reasons why your doctor, the hospital, and we think it is right (medically appropriate) for you to be discharged on that date.

Legal Terms	This written explanation is called the “Detailed Notice of Discharge.” You can get a sample of this notice by calling Customer Care (phone numbers are printed on the back cover of this booklet) or 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. (TTY users should call 1-877-486-2048.) Or you can see a sample notice online at http://www.cms.hhs.gov/BNI/
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Step 3: Within one full day after it has all the needed information, the Quality Improvement Organization will give you its answer to your appeal.

What happens if the answer is yes?

- If the review organization says yes to your appeal, **we must keep providing your covered inpatient hospital services for as long as these services are medically necessary.**
- You will have to keep paying your share of the costs (such as deductibles or copayments, if these apply). In addition, there may be limitations on your covered hospital services. (See Chapter 4 of this booklet).

What happens if the answer is no?

- If the review organization says no to your appeal, they are saying that your planned discharge date is medically appropriate. If this happens, **our coverage for your inpatient hospital services will end** at noon on the day after the Quality Improvement Organization gives you its answer to your appeal.
- If the review organization says no to your appeal and you decide to stay in the hospital, then **you may have to pay the full cost** of hospital care you receive after noon on the day after the Quality Improvement Organization gives you its answer to your appeal.

Step 4: If the answer to your Level 1 Appeal is no, you decide if you want to make another appeal.

- If the Quality Improvement Organization has turned down your appeal, and you stay in the hospital after your planned discharge date, then you can make another appeal. Making another appeal means you are going on to “Level 2” of the appeals process.

Section 7.3	Step-by-step: How to make a Level 2 Appeal to change your hospital discharge date
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If the Quality Improvement Organization has turned down your appeal, and you stay in the hospital after your planned discharge date, then you can make a Level 2 Appeal. During a Level 2 Appeal, you ask the Quality Improvement Organization to take another look at the decision they made on your first appeal. If the Quality Improvement Organization turns down your Level 2 Appeal, you may have to pay the full cost for your stay after your planned discharge date.

Here are the steps for Level 2 of the appeal process:

Step 1: You contact the Quality Improvement Organization again and ask for another review.

- You must ask for this review **within 60 calendar days** after the day when the Quality Improvement Organization said no to your Level 1 Appeal. You can ask for this review only if you stayed in the hospital after the date that your coverage for the care ended.

Step 2: The Quality Improvement Organization does a second review of your situation.

- Reviewers at the Quality Improvement Organization will take another careful look at all of the information related to your appeal.

Step 3: Within 14 calendar days, the Quality Improvement Organization reviewers will decide on your appeal and tell you their decision.

If the review organization says yes:

- **We must reimburse you** for our share of the costs of hospital care you have received since noon on the day after the date your first appeal was turned down by the Quality Improvement Organization. **We must continue providing coverage for your inpatient hospital care for as long as it is medically necessary.**
- You must continue to pay your share of the costs and coverage limitations may apply.

If the review organization says no:

- It means they agree with the decision they made on your Level 1 Appeal and will not change it. This is called "upholding the decision."
- The notice you get will tell you in writing what you can do if you wish to continue with the review process. It will give you the details about how to go on to the next level of appeal, which is handled by a judge.

Step 4: If the answer is no, you will need to decide whether you want to take your appeal further by going on to Level 3.

- There are three additional levels in the appeals process after Level 2 (for a total of five levels of appeal). If the review organization turns down your Level 2 Appeal, you can choose whether to accept that decision or whether to go on to Level 3 and make another appeal. At Level 3, your appeal is reviewed by a judge.
- Section 9 in this chapter tells more about Levels 3, 4, and 5 of the appeals process.

Section 7.4 What if you miss the deadline for making your Level 1 Appeal?

You can appeal to us instead

As explained above in Section 7.2, you must act quickly to contact the Quality Improvement Organization to start your first appeal of your hospital discharge. ("Quickly" means before you leave the hospital and no later than your planned discharge date.) If you miss the deadline for contacting this organization, there is another way to make your appeal.

If you use this other way of making your appeal, the first two levels of appeal are different.

Step-by-Step: How to make a Level 1 Alternate Appeal

If you miss the deadline for contacting the Quality Improvement Organization, you can make an appeal to us, asking for a "fast review." A fast review is an appeal that uses the fast deadlines instead of the standard deadlines.

Legal Terms	A "fast" review (or "fast appeal") is also called an "expedited appeal" .
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Step 1: Contact us and ask for a "fast review."

- For details on how to contact us, go to Chapter 2, Section 1 and look for the section called, How to contact us when you are making an appeal about your medical care.
- **Be sure to ask for a "fast review."** This means you are asking us to give you an answer using the "fast" deadlines rather than the "standard" deadlines.

Step 2: We do a "fast" review of your planned discharge date, checking to see if it was medically appropriate.

- During this review, we take a look at all of the information about your hospital stay. We check to see if your planned discharge date was medically appropriate. We will check to see if the decision about when you should leave the hospital was fair and followed all the rules.
- In this situation, we will use the "fast" deadlines rather than the standard deadlines for giving you the answer to this review.

Step 3: We give you our decision within 72 hours after you ask for a "fast review" ("fast appeal").

- **If we say yes to your fast appeal,** it means we have agreed with you that you still need to be in the hospital after the discharge date, and will keep providing your covered inpatient hospital services for as long as it is medically necessary. It also means that we have agreed to reimburse you for our share of the costs of care you have received since the date when we said your coverage would end. (You must pay your share of the costs and there may be coverage limitations that apply.)
- **If we say no to your fast appeal,** we are saying that your planned discharge date was medically appropriate. Our coverage for your inpatient hospital services ends as of the day we said coverage would end.
 - If you stayed in the hospital after your planned discharge date, then **you may have to pay the full cost** of hospital care you received after the planned discharge date.

Step 4: If we say no to your fast appeal, your case will automatically be sent on to the next level of the appeals process.

- To make sure we were following all the rules when we said no to your fast appeal, **we are required to send your appeal to the “Independent Review Organization.”** When we do this, it means that you are automatically going on to Level 2 of the appeals process.

Step-by-Step: How to make a Level 2 Alternate Appeal

If we say no to your Level 1 Appeal, your case will automatically be sent on to the next level of the appeals process. During the Level 2 Appeal, the **Independent Review Organization** reviews the decision we made when we said no to your “fast appeal.” This organization decides whether the decision we made should be changed.

**Legal
Terms**

The formal name for the **“Independent Review Organization”** is the “Independent Review Entity.” It is sometimes called the **“IRE.”**

Step 1: We will automatically forward your case to the Independent Review Organization.

- We are required to send the information for your Level 2 Appeal to the Independent Review Organization within 24 hours of when we tell you that we are saying no to your first appeal. (If you think we are not meeting this deadline or other deadlines, you can make a complaint. The complaint process is different from the appeal process. Section 10 of this chapter tells how to make a complaint.)

Step 2: The Independent Review Organization does a “fast review” of your appeal. The reviewers give you an answer within 72 hours.

- The Independent Review Organization is an independent organization that is hired by Medicare.** This organization is not connected with our plan and it is not a government agency. This organization is a company chosen by Medicare to handle the job of being the Independent Review Organization. Medicare oversees its work.
- Reviewers at the Independent Review Organization will take a careful look at all of the information related to your appeal of your hospital discharge.
- If this organization says yes to your appeal,** then we must reimburse you (pay you back) for our share of the costs of hospital care you have received since the date of your planned discharge. We must also continue the plan's coverage of your inpatient hospital services for as long as it is medically necessary. You must continue to pay your share of the costs. If there are coverage limitations, these could limit how much we would reimburse or how long we would continue to cover your services.
- If this organization says no to your appeal,** it means they agree with us that your planned hospital discharge date was medically appropriate.
 - The notice you get from the Independent Review Organization will tell you in writing what you can do if you wish to continue with the review process. It will give you the details about how to go on to a Level 3 Appeal, which is handled by a judge.

Step 3: If the Independent Review Organization turns down your appeal, you choose whether you want to take your appeal further.

- There are three additional levels in the appeals process after Level 2 (for a total of five levels of appeal). If reviewers say no to your Level 2 Appeal, you decide whether to accept their decision or go on to Level 3 and make a third appeal.
- Section 9 in this chapter tells more about Levels 3, 4, and 5 of the appeals process.

SECTION 8 How to ask us to keep covering certain medical services if you think your coverage is ending too soon

Section 8.1	This section is about three services <u>only</u>: Home health care, skilled nursing facility care, and Comprehensive Outpatient Rehabilitation Facility (CORF) services
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This section is about the following types of care only:

- **Home health care services** you are getting.
- **Skilled nursing care** you are getting as a patient in a skilled nursing facility. (To learn about requirements for being considered a “skilled nursing facility,” see Chapter 12, Definitions of important words.)
- **Rehabilitation care** you are getting as an outpatient at a Medicare-approved Comprehensive Outpatient Rehabilitation Facility (CORF). Usually, this means you are getting treatment for an illness or accident, or you are recovering from a major operation. (For more information about this type of facility, see Chapter 12, Definitions of important words.)

When you are getting any of these types of care, you have the right to keep getting your covered services for that type of care for as long as the care is needed to diagnose and treat your illness or injury. For more information on your covered services, including your share of the cost and any limitations to coverage that may apply, see Chapter 4 of this booklet: Medical Benefits Chart (what is covered and what you pay).

When we decide it is time to stop covering any of the three types of care for you, we are required to tell you in advance. When your coverage for that care ends, we will stop paying our share of the cost for your care.

If you think we are ending the coverage of your care too soon, **you can appeal our decision**. This section tells you how to ask for an appeal.

Section 8.2	We will tell you in advance when your coverage will be ending
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1. **You receive a notice in writing.** At least two days before our plan is going to stop covering your care, the agency or facility that is providing your care will give you a notice.
 - The written notice tells you the date when we will stop covering the care for you.

- The written notice also tells what you can do if you want to ask our plan to change this decision about when to end your care, and keep covering it for a longer period of time.

Legal Terms	In telling you what you can do, the written notice is telling how you can request a “fast-track appeal.” Requesting a fast-track appeal is a formal, legal way to request a change to our coverage decision about when to stop your care. (Section 8.3 below tells how you can request a fast-track appeal.)
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Legal Terms	The written notice is called the “Notice of Medicare Non-Coverage.” To get a sample copy, call Customer Care (phone numbers are printed on the back cover of this booklet) or 1-800-MEDICARE (1-800-633-4227, 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.). Or see a copy online at http://www.cms.hhs.gov/BNI/
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2. You must sign the written notice to show that you received it.

- You or someone who is acting on your behalf must sign the notice. (Section 4 tells how you can give written permission to someone else to act as your representative.)
- Signing the notice shows only that you have received the information about when your coverage will stop. **Signing it does not mean you agree** with the plan that it's time to stop getting the care.

Section 8.3	Step-by-step: How to make a Level 1 Appeal to have our plan cover your care for a longer time
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If you want to ask us to cover your care for a longer period of time, you will need to use the appeals process to make this request. Before you start, understand what you need to do and what the deadlines are.

- **Follow the process.** Each step in the first two levels of the appeals process is explained below.
- **Meet the deadlines.** The deadlines are important. Be sure that you understand and follow the deadlines that apply to things you must do. There are also deadlines our plan must follow. (If you think we are not meeting our deadlines, you can file a complaint. Section 10 of this chapter tells you how to file a complaint.)
- **Ask for help if you need it.** If you have questions or need help at any time, please call Customer Care (phone numbers are printed on the back cover of this booklet). Or call your State Health Insurance Assistance Program, a government organization that provides personalized assistance (see Section 2 of this chapter).

During a Level 1 Appeal, the Quality Improvement Organization reviews your appeal and decides whether to change the decision made by our plan.

Step 1: Make your Level 1 Appeal: contact the Quality Improvement Organization in your state and ask for a review. You must act quickly.

What is the Quality Improvement Organization?

- This organization is a group of doctors and other health care experts who are paid by the federal government. These experts are not part of our plan. They check on the quality of care received by people with Medicare and review plan decisions about when it's time to stop covering certain kinds of medical care.

How can you contact this organization?

- The written notice you received tells you how to reach this organization. (Or find the name, address, and phone number of the Quality Improvement Organization for your state in "Exhibit A" in the back of this booklet.)

What should you ask for?

- Ask this organization to do an independent review of whether it is medically appropriate for us to end coverage for your medical services.

Your deadline for contacting this organization.

- You must contact the Quality Improvement Organization to start your appeal no later than noon of the day after you receive the written notice telling you when we will stop covering your care.
- If you miss the deadline for contacting the Quality Improvement Organization about your appeal, you can make your appeal directly to us instead. For details about this other way to make your appeal, see Section 8.5.

Step 2: The Quality Improvement Organization conducts an independent review of your case.

What happens during this review?

- Health professionals at the Quality Improvement Organization (we will call them “the reviewers” for short) will ask you (or your representative) why you believe coverage for the services should continue. You don't have to prepare anything in writing, but you may do so if you wish.
- The review organization will also look at your medical information, talk with your doctor, and review information that our plan has given to them.
- By the end of the day the reviewers informed us of your appeal, and you will also get a written notice from us that explains in detail our reasons for ending our coverage for your services.

Legal Terms	This notice is called the “Detailed Explanation of Non-Coverage.”
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Step 3: Within one full day after they have all the information they need, the reviewers will tell you their decision.

What happens if the reviewers say yes to your appeal?

- If the reviewers say yes to your appeal, then **we must keep providing your covered services for as long as it is medically necessary.**
- You will have to keep paying your share of the costs (such as deductibles or copayments, if these apply). In addition, there may be limitations on your covered services (see Chapter 4 of this booklet).

What happens if the reviewers say no to your appeal?

- If the reviewers say no to your appeal, then **your coverage will end on the date we have told you.** We will stop paying its share of the costs of this care.
- If you decide to keep getting the home health care, or skilled nursing facility care, or Comprehensive Outpatient Rehabilitation Facility (CORF) services after this date when your coverage ends, then **you will have to pay the full cost** of this care yourself.

Step 4: If the answer to your Level 1 Appeal is no, you decide if you want to make another appeal.

- This first appeal you make is “Level 1” of the appeals process. If reviewers say no to your Level 1 Appeal – and you choose to continue getting care after your coverage for the care has ended – then you can make another appeal.
- Making another appeal means you are going on to “Level 2” of the appeals process.

Section 8.4 Step-by-step: How to make a Level 2 Appeal to have our plan cover your care for a longer time

If the Quality Improvement Organization has turned down your appeal and you choose to continue getting care after your coverage for the care has ended, then you can make a Level 2 Appeal. During a Level 2 Appeal, you ask the Quality Improvement Organization to take another look at the decision they made on your first appeal. If the Quality Improvement Organization turns down your Level 2 Appeal, you may have to pay the full cost for your home health care, or skilled nursing facility care, or Comprehensive Outpatient Rehabilitation Facility (CORF) services after the date when we said your coverage would end.

Here are the steps for Level 2 of the appeal process:

Step 1: You contact the Quality Improvement Organization again and ask for another review.

- You must ask for this review **within 60 days** after the day when the Quality Improvement Organization said no to your Level 1 Appeal. You can ask for this review only if you continued getting care after the date that your coverage for the care ended.

Step 2: The Quality Improvement Organization does a second review of your situation.

- Reviewers at the Quality Improvement Organization will take another careful look at all of the information related to your appeal.

Step 3: Within 14 days, the Quality Improvement Organization reviewers will decide on your appeal and tell you their decision.

What happens if the review organization says yes to your appeal?

- **We must reimburse you** for our share of the costs of care you have received since the date when we said your coverage would end. **We must continue providing coverage** for the care for as long as it is medically necessary.
- You must continue to pay your share of the costs and there may be coverage limitations that apply.

What happens if the review organization says no?

- It means they agree with the decision we made to your Level 1 Appeal and will not change it.
- The notice you get will tell you in writing what you can do if you wish to continue with the review process. It will give you the details about how to go on to the next level of appeal, which is handled by a judge.

Step 4: If the answer is no, you will need to decide whether you want to take your appeal further.

- There are three additional levels of appeal after Level 2, for a total of five levels of appeal. If reviewers turn down your Level 2 Appeal, you can choose whether to accept that decision or to go on to Level 3 and make another appeal. At Level 3, your appeal is reviewed by a judge.
- Section 9 in this chapter tells more about Levels 3, 4, and 5 of the appeals process.

Section 8.5 What if you miss the deadline for making your Level 1 Appeal?

You can appeal to us instead

As explained above in Section 8.3, you must act quickly to contact the Quality Improvement Organization to start your first appeal (within a day or two, at the most). If you miss the deadline for contacting this organization, there is another way to make your appeal. If you use this other way of making your appeal, the first two levels of appeal are different.

Step-by-Step: How to make a Level 1 Alternate Appeal

If you miss the deadline for contacting the Quality Improvement Organization, you can make an appeal to us, asking for a “fast review.” A fast review is an appeal that uses the fast deadlines instead of the standard deadlines. Here are the steps for a Level 1 Alternate Appeal:

Legal Terms	A “fast” review (or “fast appeal”) is also called an “expedited appeal” .
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Step 1: Contact us and ask for a “fast review.”

- For details on how to contact us, go to Chapter 2, Section 1 and look for the section called, How to contact us when you are making an appeal about your medical care.
- **Be sure to ask for a “fast review.”** This means you are asking us to give you an answer using the “fast” deadlines rather than the “standard” deadlines.

Step 2: We do a “fast” review of the decision we made about when to end coverage for your services.

- During this review, we take another look at all of the information about your case. We check to see if we were following all the rules when we set the date for ending the plan's coverage for services you were receiving.
- We will use the “fast” deadlines rather than the standard deadlines for giving you the answer to this review. (Usually, if you make an appeal to our plan and ask for a “fast review,” we are allowed to decide whether to agree to your request and give you a “fast review.” But in this situation, the rules require us to give you a fast response if you ask for it.)

Step 3: We give you our decision within 72 hours after you ask for a “fast review” (“fast appeal”).

- **If we say yes to your fast appeal,** it means we have agreed with you that you need services longer, and will keep providing your covered services for as long as it is medically necessary. It also means that we have agreed to reimburse you for our share of the costs of care you have received since the date when we said your coverage would end. (You must pay your share of the costs and there may be coverage limitations that apply.)
- **If we say no to your fast appeal,** then your coverage will end on the date we told you and we will not pay any share of the costs after this date. We will stop paying its share of the costs of this care.
- If you continued to get home health care, or skilled nursing facility care, or Comprehensive Outpatient Rehabilitation Facility (CORF) services after the date when we said your coverage would end, then **you will have to pay the full cost** of this care yourself.

Step 4: If we say no to your fast appeal, your case will automatically go on to the next level of the appeals process.

- To make sure we were following all the rules when we said no to your fast appeal, **we are required to send your appeal to the “Independent Review Organization.”** When we do this, it means that you are automatically going on to Level 2 of the appeals process.

Step-by-Step: How to make a Level 2 Alternate Appeal

If we say no to your Level 1 Appeal, your case will automatically be sent on to the next level of the appeals process. During the Level 2 Appeal, the **Independent Review Organization** reviews the decision we made when we said no to your “fast appeal.” This organization decides whether the decision we made should be changed.

Legal Terms	The formal name for the “Independent Review Organization” is the “Independent Review Entity.” It is sometimes called the “IRE.”
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Step 1: We will automatically forward your case to the Independent Review Organization.

- We are required to send the information for your Level 2 Appeal to the Independent Review Organization within 24 hours of when we tell you that we are saying no to your first appeal. (If you think we are not meeting this deadline or other deadlines, you can make a complaint. The complaint process is different from the appeal process. Section 10 of this chapter tells how to make a complaint.)

Step 2: The Independent Review Organization does a “fast review” of your appeal. The reviewers give you an answer within 72 hours.

- **The Independent Review Organization is an independent organization that is hired by Medicare.** This organization is not connected with our plan and it is not a government agency. This organization is a company chosen by Medicare to handle the job of being the Independent Review Organization. Medicare oversees its work.
- Reviewers at the Independent Review Organization will take a careful look at all of the information related to your appeal.
- **If this organization says yes to your appeal,** then we must reimburse you (pay you back) for our share of the costs of care you have received since the date when we said your coverage would end. We must also continue to cover the care for as long as it is medically necessary. You must continue to pay your share of the costs. If there are coverage limitations, these could limit how much we would reimburse or how long we would continue to cover your services.
- **If this organization says no to your appeal,** it means they agree with the decision our plan made to your first appeal and will not change it.
 - The notice you get from the Independent Review Organization will tell you in writing what you can do if you wish to continue with the review process. It will give you the details about how to go on to a Level 3 Appeal.

Step 3: If the Independent Review Organization turns down your appeal, you choose whether you want to take your appeal further.

- There are three additional levels of appeal after Level 2, for a total of five levels of appeal. If reviewers say no to your Level 2 Appeal, you can choose whether to accept that decision or whether to go on to Level 3 and make another appeal. At Level 3, your appeal is reviewed by a judge.
- Section 9 in this chapter tells more about Levels 3, 4, and 5 of the appeals process.

SECTION 9 Taking your appeal to Level 3 and beyond

Section 9.1 Levels of Appeal 3, 4, and 5 for Medical Service Appeals

This section may be appropriate for you if you have made a Level 1 Appeal and a Level 2 Appeal, and both of your appeals have been turned down.

If the dollar value of the item or medical service you have appealed meets certain minimum levels, you may be able to go on to additional levels of appeal. If the dollar value is less than the minimum level, you cannot appeal any further. If the dollar value is high enough, the written response you receive to your Level 2 Appeal will explain who to contact and what to do to ask for a Level 3 Appeal.

For most situations that involve appeals, the last three levels of appeal work in much the same way. Here is who handles the review of your appeal at each of these levels.

Level 3 Appeal A judge who works for the federal government will review your appeal and give you an answer. This judge is called an “Administrative Law Judge.”

- **If the Administrative Law Judge says yes to your appeal, the appeals process may or may not be over -** We will decide whether to appeal this decision to Level 4. Unlike a decision at Level 2 (Independent Review Organization), we have the right to appeal a Level 3 decision that is favorable to you.
 - If we decide not to appeal the decision, we must authorize or provide you with the service within 60 calendar days after receiving the judge's decision.
 - If we decide to appeal the decision, we will send you a copy of the Level 4 Appeal request with any accompanying documents. We may wait for the Level 4 Appeal decision before authorizing or providing the service in dispute.
- **If the Administrative Law Judge says no to your appeal, the appeals process may or may not be over.**
 - If you decide to accept this decision that turns down your appeal, the appeals process is over.
 - If you do not want to accept the decision, you can continue to the next level of the review process. If the administrative law judge says no to your appeal, the notice you get will tell you what to do next if you choose to continue with your appeal.

Level 4 Appeal The **Appeals Council** will review your appeal and give you an answer. The Appeals Council works for the federal government.

- **If the answer is yes, or if the Appeals Council denies our request to review a favorable Level 3 Appeal decision, the appeals process may or may not be over -** We will decide whether to appeal this decision to Level 5. Unlike a decision at Level 2 (Independent Review Organization), we have the right to appeal a Level 4 decision that is favorable to you.
 - If we decide not to appeal the decision, we must authorize or provide you with the service within 60 calendar days after receiving the Appeals Council's decision.
 - If we decide to appeal the decision, we will let you know in writing.
- **If the answer is no or if the Appeals Council denies the review request, the appeals process may or may not be over.**
 - If you decide to accept this decision that turns down your appeal, the appeals process is over.
 - If you do not want to accept the decision, you might be able to continue to the next level of the review process. If the Appeals Council says no to your appeal, the notice you get will tell you whether the rules

allow you to go on to a Level 5 Appeal. If the rules allow you to go on, the written notice will also tell you who to contact and what to do next if you choose to continue with your appeal.

Level 5 Appeal A judge at the **Federal District Court** will review your appeal.

- This is the last step of the administrative appeals process.

Section 9.2 Levels of Appeal 3, 4, and 5 for Part D Drug Appeals

This section may be appropriate for you if you have made a Level 1 Appeal and a Level 2 Appeal, and both of your appeals have been turned down.

If the value of the drug you have appealed meets a certain dollar amount, you may be able to go on to additional levels of appeal. If the dollar amount is less than the minimum level, you cannot appeal any further. The written response you receive to your Level 2 Appeal will explain who to contact and what to do to ask for a Level 3 Appeal.

For most situations that involve appeals, the last three levels of appeal work in much the same way. Here is who handles the review of your appeal at each of these levels.

Level 3 Appeal A judge who works for the federal government will review your appeal and give you an answer. This judge is called an “Administrative Law Judge.”

- **If the answer is yes, the appeals process is over.** What you asked for in the appeal has been approved. We must **authorize or provide the drug coverage** that was approved by the Administrative Law Judge **within 72 hours (24 hours for expedited appeals) or make payment no later than 30 calendar days** after we receive the decision.
- **If the answer is no, the appeals process may or may not be over.**
 - If you decide to accept this decision that turns down your appeal, the appeals process is over.
 - If you do not want to accept the decision, you can continue to the next level of the review process. If the administrative law judge says no to your appeal, the notice you get will tell you what to do next if you choose to continue with your appeal.

Level 4 Appeal The **Appeals Council** will review your appeal and give you an answer. The Appeals Council works for the federal government.

- **If the answer is yes, the appeals process is over.** What you asked for in the appeal has been approved. We must **authorize or provide the drug coverage** that was approved by the Appeals Council **within 72 hours (24 hours for expedited appeals) or make payment no later than 30 calendar days** after we receive the decision.
- **If the answer is no, the appeals process may or may not be over.**
 - If you decide to accept this decision that turns down your appeal, the appeals process is over.
 - If you do not want to accept the decision, you might be able to continue to the next level of the review process. If the Appeals Council says no to your appeal or denies your request to review the appeal, the notice you get will tell you whether the rules allow you to go on to a Level 5 Appeal. If the rules allow

you to go on, the written notice will also tell you who to contact and what to do next if you choose to continue with your appeal.

Level 5 Appeal A judge at the **Federal District Court** will review your appeal.

- This is the last step of the appeals process.

MAKING COMPLAINTS

SECTION 10 How to make a complaint about quality of care, waiting times, customer service, or other concerns



If your problem is about decisions related to benefits, coverage, or payment, then this section is not for you. Instead, you need to use the process for coverage decisions and appeals. Go to Section 4 of this chapter.

Section 10.1 What kinds of problems are handled by the complaint process?

This section explains how to use the process for making complaints. The complaint process is used for certain types of problems only. This includes problems related to quality of care, waiting times, and the customer service you receive. Here are examples of the kinds of problems handled by the complaint process.

If you have any of these kinds of problems, you can "make a complaint"

Quality of your medical care

- Are you unhappy with the quality of the care you have received (including care in the hospital)?

Respecting your privacy

- Do you believe that someone did not respect your right to privacy or shared information about you that you feel should be confidential?

Disrespect, poor customer service, or other negative behaviors

- Has someone been rude or disrespectful to you?
- Are you unhappy with how our Customer Care has treated you?
- Do you feel you are being encouraged to leave the plan?

The next page has more examples of possible reasons for making a complaint

Possible complaints (continued)

Waiting times

- Are you having trouble getting an appointment, or waiting too long to get it?
- Have you been kept waiting too long by doctors, pharmacists, or other health professionals? Or by our Customer Care or other staff at the plan?
 - Examples include waiting too long on the phone, in the waiting room, when getting a prescription, or in the exam room.

Cleanliness

- Are you unhappy with the cleanliness or condition of a clinic, hospital, or doctor's office?

Information you get from us

- Do you believe we have not given you a notice that we are required to give?
- Do you think written information we have given you is hard to understand?

These types of complaints are all related to the timeliness of our actions related to coverage decisions and appeals

The process of asking for a coverage decision and making appeals is explained in Sections 4-9 of this chapter. If you are asking for a decision or making an appeal, you use that process, not the complaint process.

However, if you have already asked us for a coverage decision or made an appeal, and you think that we are not responding quickly enough, you can also make a complaint about our slowness. Here are examples:

- If you have asked us to give you a "fast coverage decision" or a "fast appeal", and we have said we will not, you can make a complaint.
- If you believe we are not meeting the deadlines for giving you a coverage decision or an answer to an appeal you have made, you can make a complaint.
- When a coverage decision we made is reviewed and we are told that we must cover or reimburse you for certain medical services or drugs, there are deadlines that apply. If you think we are not meeting these deadlines, you can make a complaint.
- When we do not give you a decision on time, we are required to forward your case to the Independent Review Organization. If we do not do that within the required deadline, you can make a complaint.

Section 10.2 The formal for "making a complaint" is "filing a grievance"

Legal Terms

- What this section calls a "**complaint**" is also called a "**grievance**."
- Another term for "**making a complaint**" is "**filing a grievance**."
- Another way to say "**using the process for complaints**" is "**using the process for filing a grievance**."

Section 10.3 Step-by-step: Making a complaint

Step 1: Contact us promptly – either by phone or in writing.

- **Usually, calling Customer Care is the first step.** If there is anything else you need to do, Customer Care will let you know. 1-800-457-4708 TTY 711 from 8 a.m. to 8 p.m. seven days a week from Oct. 1 – Feb. 14 and 8 a.m. to 8 p.m. Monday-Friday from Feb. 15 – Sept. 30.
- **If you do not wish to call (or you called and were not satisfied), you can put your complaint in writing and send it to us.** If you put your complaint in writing, we will respond to your complaint in writing.

Grievance process

You or your representative may file your concerns in writing or verbally.

Please follow the grievance process described below:

When filing a grievance, please provide the following information:

Your name, address, telephone number, and member identification number; you or your authorized representative's signature and the date signed; a summary of the grievance and any previous contact with us; and a description of the action you are requesting. If you or your authorized representative require assistance in preparing and submitting your written grievance, contact Customer Care at the number shown in Chapter 2 of this booklet.

You may request an expedited (fast) grievance if:

- You disagree with our decision to extend the timeframe to make an initial (standard) organization/coverage determination or reconsideration.
- We deny your request for a 72-hour/fast (expedited) organization/coverage determination or reconsiderations/redeterminations.
- We deny your request for a 72-hour/fast (expedited) appeal.

If you mail the request for an expedited grievance, we will provide oral acknowledgement upon receipt. We will make a determination within 24 hours of receipt of your request.

- **Whether you call or write, you should contact Customer Care right away.** The complaint must be made within 60 calendar days after you had the problem you want to complain about.
- **If you are making a complaint because we denied your request for a "fast coverage decision" or a "fast appeal", we will automatically give you a "fast" complaint.** If you have a "fast" complaint, it means we will give you **an answer within 24 hours.**

Legal Terms

What this section calls a "**fast complaint**" is also called an "**expedited grievance**."

Step 2: We look into your complaint and give you our answer.

- **If possible, we will answer you right away.** If you call us with a complaint, we may be able to give you an answer on the same phone call. If your health condition requires us to answer quickly, we will do that.
- **Most complaints are answered in 30 calendar days.** If we need more information and the delay is in your best interest or if you ask for more time, we can take up to 14 more calendar days (44 calendar days total) to answer your complaint.

- **If we do not agree** with some or all of your complaint or don't take responsibility for the problem you are complaining about, we will let you know. Our response will include our reasons for this answer. We must respond whether we agree with the complaint or not.

Section 10.4 You can also make complaints about quality of care to the Quality Improvement Organization

You can make your complaint about the quality of care you received to us by using the step-by-step process outlined above.

When your complaint is about quality of care, you also have two extra options:

- **You can make your complaint to the Quality Improvement Organization.** If you prefer, you can make your complaint about the quality of care you received directly to this organization (without making the complaint to us).
 - The Quality Improvement Organization is a group of practicing doctors and other health care experts paid by the federal government to check and improve the care given to Medicare patients.
 - To find the name, address, and phone number of the Quality Improvement Organization for your state, look in Chapter 2, Section 4, of this booklet. If you make a complaint to this organization, we will work with them to resolve your complaint.
- **Or you can make your complaint to both at the same time.** If you wish, you can make your complaint about quality of care to us and also to the Quality Improvement Organization.

Section 10.5 You can also tell Medicare about your complaint

You can submit a complaint about Humana Gold Plus H0108-004 (HMO) directly to Medicare. To submit a complaint to Medicare, go to www.medicare.gov/MedicareComplaintForm/home.aspx. Medicare takes your complaints seriously and will use this information to help improve the quality of the Medicare program.

If you have any other feedback or concerns, or if you feel the plan is not addressing your issue, please call 1-800-MEDICARE (1-800-633-4227). TTY/TDD users can call 1-877-486-2048.

Chapter 10. Ending your membership in the plan

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SECTION 1 Introduction

Section 1.1 This chapter focuses on ending your membership in our plan

Ending your membership in Humana Gold Plus H0108-004 (HMO) may be **voluntary** (your own choice) or **involuntary** (not your own choice):

- You might leave our plan because you have decided that you want to leave.
 - There are only certain times during the year, or certain situations, when you may voluntarily end your membership in the plan. Section 2 tells you when you can end your membership in the plan.
 - The process for voluntarily ending your membership varies depending on what type of new coverage you are choosing. Section 3 tells you how to end your membership in each situation.
- There are also limited situations where you do not choose to leave, but we are required to end your membership. Section 5 tells you about situations when we must end your membership.

If you are leaving our plan, you must continue to get your medical care and prescription drugs through our plan until your membership ends.

SECTION 2 When can you end your membership in our plan?

You may end your membership in our plan only during certain times of the year, known as enrollment periods. All members have the opportunity to leave the plan during the Annual Enrollment Period and during the annual Medicare Advantage Disenrollment Period. In certain situations, you may also be eligible to leave the plan at other times of the year.

Section 2.1 You can end your membership during the Annual Enrollment Period

You can end your membership during the **Annual Enrollment Period** (also known as the “Annual Coordinated Election Period”). This is the time when you should review your health and drug coverage and make a decision about your coverage for the upcoming year.

- **When is the Annual Enrollment Period?** This happens from October 15 to December 7.
- **What type of plan can you switch to during the Annual Enrollment Period?** During this time, you can review your health coverage and your prescription drug coverage. You can choose to keep your current coverage or make changes to your coverage for the upcoming year. If you decide to change to a new plan, you can choose any of the following types of plans:
 - Another Medicare health plan. (You can choose a plan that covers prescription drugs or one that does not cover prescription drugs.)
 - Original Medicare with a separate Medicare prescription drug plan.
 - - or - Original Medicare without a separate Medicare prescription drug plan.
- **If you receive "Extra Help" from Medicare to pay for your prescription drugs:** If you switch to Original Medicare and do not enroll in a separate Medicare prescription drug plan, Medicare may enroll you in a drug plan, unless you have opted out of automatic enrollment.

Note: If you disenroll from Medicare prescription drug coverage and go without creditable prescription drug coverage, you may need to pay a late enrollment penalty if you join a Medicare drug plan later. (“Creditable” coverage means the coverage is expected to pay, on average, at least as much as Medicare's

standard prescription drug coverage.) See Chapter 6, Section 10 for more information about the late enrollment penalty.

- **When will your membership end?** Your membership will end when your new plan's coverage begins on January 1.

Section 2.2	You can end your membership during the annual Medicare Advantage Disenrollment Period, but your choices are more limited
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You have the opportunity to make one change to your health coverage during the annual **Medicare Advantage Disenrollment Period**.

- **When is the annual Medicare Advantage Disenrollment Period?** This happens every year from January 1 to February 14.
- **What type of plan can you switch to during the annual Medicare Advantage Disenrollment Period?** During this time, you can cancel your Medicare Advantage plan enrollment and switch to Original Medicare. If you choose to switch to Original Medicare during this period, you have until February 14 to join a separate Medicare prescription drug plan to add drug coverage.
- **When will your membership end?** Your membership will end on the first day of the month after we get your request to switch to Original Medicare. If you also choose to enroll in a Medicare prescription drug plan, your membership in the drug plan will begin the first day of the month after the drug plan gets your enrollment request.

Section 2.3	In certain situations, you can end your membership during a Special Enrollment Period
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In certain situations, members of Humana Gold Plus H0108-004 (HMO) may be eligible to end their membership at other times of the year. This is known as a **Special Enrollment Period**.

- **Who is eligible for a Special Enrollment Period?** If any of the following situations apply to you, you are eligible to end your membership during a Special Enrollment Period. These are just examples, for the full list you can contact the plan, call Medicare, or visit the Medicare website (<http://www.medicare.gov>):
 - Usually, when you have moved.
 - If you have Medicaid.
 - If you are eligible for "Extra Help" with paying for your Medicare prescriptions.
 - If we violate our contract with you.
 - If you are getting care in an institution, such as a nursing home or long-term care hospital.
 - If you enroll in the Program of All-inclusive Care for the Elderly (PACE).
- **When are Special Enrollment Periods?** The enrollment periods vary depending on your situation.
- **What can you do?** To find out if you are eligible for a Special Enrollment Period, please call Medicare at 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users call 1-877-486-2048. If you are eligible to end your membership because of a special situation, you can choose to change both your Medicare health coverage and prescription drug coverage. This means you can choose any of the following types of plans:
 - Another Medicare health plan. (You can choose a plan that covers prescription drugs or one that does not cover prescription drugs.)
 - Original Medicare with a separate Medicare prescription drug plan.
 - - or - Original Medicare without a separate Medicare prescription drug plan.

- > **If you receive "Extra Help" from Medicare to pay for your prescription drugs:** If you switch to Original Medicare and do not enroll in a separate Medicare prescription drug plan, Medicare may enroll you in a drug plan, unless you have opted out of automatic enrollment.

Note: If you disenroll from Medicare prescription drug coverage and go without creditable prescription drug coverage, you may need to pay a late enrollment penalty if you join a Medicare drug plan later. ("Creditable" coverage means the coverage is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage.) See Chapter 6, Section 10 for more information about the late enrollment penalty.

- **When will your membership end?** Your membership will usually end on the first day of the month after we receive your request to change your plan.

Section 2.4	Where can you get more information about when you can end your membership?
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If you have any questions or would like more information on when you can end your membership:

- You can **call Customer Care** (phone numbers are printed on the back cover of this booklet).
- You can find the information in the **Medicare & You 2014** Handbook.
 - Everyone with Medicare receives a copy of Medicare & You each fall. Those new to Medicare receive it within a month after first signing up.
 - You can also download a copy from the Medicare website (<http://www.medicare.gov>). Or, you can order a printed copy by calling Medicare at the number below.
- You can contact **Medicare** at 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.

SECTION 3 How do you end your membership in our plan?

Section 3.1	Usually, you end your membership by enrolling in another plan
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Usually, to end your membership in our plan, you simply enroll in another Medicare plan during one of the enrollment periods (see Section 2 in this chapter for information about the enrollment periods). However, if you want to switch from our plan to Original Medicare without a Medicare prescription drug plan, you must ask to be disenrolled from our plan. There are two ways you can ask to be disenrolled:

- You can make a request in writing to us. Contact Customer Care if you need more information on how to do this (phone numbers are printed on the back cover of this booklet).
- --or-- You can contact Medicare at 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week. TTY users should call 1-877-486-2048.

Note: If you disenroll from Medicare prescription drug coverage and go without creditable prescription drug coverage, you may need to pay a late enrollment penalty if you join a Medicare drug plan later. ("Creditable" coverage means the coverage is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage.) See Chapter 6, Section 10 for more information about the late enrollment penalty.

The table below explains how you should end your membership in our plan.

If you would like to switch from our plan to:	This is what you should do:
<ul style="list-style-type: none"> Another Medicare health plan. 	<ul style="list-style-type: none"> Enroll in the new Medicare health plan. You will automatically be disenrolled from Humana Gold Plus H0108-004 (HMO) when your new plan's coverage begins.
<ul style="list-style-type: none"> Original Medicare <u>with</u> a separate Medicare prescription drug plan. 	<ul style="list-style-type: none"> Enroll in the new Medicare prescription drug plan. You will automatically be disenrolled from Humana Gold Plus H0108-004 (HMO) when your new plan's coverage begins.
<ul style="list-style-type: none"> Original Medicare <u>without</u> a separate Medicare prescription drug plan. <ul style="list-style-type: none"> Note: If you disenroll from a Medicare prescription drug plan and go without creditable prescription drug coverage, you may need to pay a late enrollment penalty if you join a Medicare drug plan later. See Chapter 6, Section 10 for more information about the late enrollment penalty. 	<ul style="list-style-type: none"> Send us a written request to disenroll. Contact Customer Care if you need more information on how to do this (phone numbers are printed on the back cover of this booklet). You can also contact Medicare at 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week, and ask to be disenrolled. TTY users should call 1-877-486-2048. You will be disenrolled from Humana Gold Plus H0108-004 (HMO) when your coverage in Original Medicare begins.

SECTION 4 Until your membership ends, you must keep getting your medical services and drugs through our plan

Section 4.1 Until your membership ends, you are still a member of our plan

If you leave Humana Gold Plus H0108-004 (HMO), it may take time before your membership ends and your new Medicare coverage goes into effect. (See Section 2 for information on when your new coverage begins.) During this time, you must continue to get your medical care and prescription drugs through our plan.

- You should continue to use our network pharmacies to get your prescriptions filled until your membership in our plan ends.** Usually, your prescription drugs are only covered if they are filled at a network pharmacy, including through our mail-order pharmacy services.
- If you are hospitalized on the day that your membership ends, your hospital stay will usually be covered by our plan until you are discharged** (even if you are discharged after your new health coverage begins).

SECTION 5 Humana Gold Plus H0108-004 (HMO) must end your membership in the plan in certain situations

Section 5.1 When must we end your membership in the plan?

Humana Gold Plus H0108-004 (HMO) must end your membership in the plan if any of the following happen:

- If you do not stay continuously enrolled in Medicare Part A and Part B.
- If you move out of our service area.
- If you are away from our service area for more than six months.
 - If you move or take a long trip, you need to call Customer Care to find out if the place you are moving or traveling to is in our plan's area. (Phone numbers for Customer Care are printed on the back cover of this booklet.)
- If you become incarcerated (go to prison).
- If you lie about or withhold information about other insurance you have that provides prescription drug coverage.
- If you intentionally give us incorrect information when you are enrolling in our plan and that information affects your eligibility for our plan. (We cannot make you leave our plan for this reason unless we get permission from Medicare first.)
- If you continuously behave in a way that is disruptive and makes it difficult for us to provide medical care for you and other members of our plan. (We cannot make you leave our plan for this reason unless we get permission from Medicare first.)
- If you let someone else use your membership card to get medical care. (We cannot make you leave our plan for this reason unless we get permission from Medicare first.)
 - If we end your membership because of this reason, Medicare may have your case investigated by the Inspector General.
- If you are required to pay the extra Part D amount because of your income and you do not pay it, Medicare will disenroll you from our plan and you will lose prescription drug coverage.

Where can you get more information?

If you have questions or would like more information on when we can end your membership:

- You can call **Customer Care** for more information (phone numbers are printed on the back cover of this booklet).

Section 5.2 We <u>cannot</u> ask you to leave our plan for any reason related to your health
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Humana Gold Plus H0108-004 (HMO) is not allowed to ask you to leave our plan for any reason related to your health.

What should you do if this happens?

If you feel that you are being asked to leave our plan because of a health-related reason, you should call Medicare at 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. You may call 24 hours a day, 7 days a week.

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Chapter 10: Ending your membership in the plan

Section 5.3	You have the right to make a complaint if we end your membership in our plan
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If we end your membership in our plan, we must tell you our reasons in writing for ending your membership. We must also explain how you can make a complaint about our decision to end your membership. You can also look in Chapter 9, Section 11 for information about how to make a complaint.

Chapter 11. Legal notices

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SECTION 1 Notice about governing law

Many laws apply to this Evidence of Coverage and some additional provisions may apply because they are required by law. This may affect your rights and responsibilities even if the laws are not included or explained in this document. The principal law that applies to this document is Title XVIII of the Social Security Act and the regulations created under the Social Security Act by the Centers for Medicare & Medicaid Services, or CMS. In addition, other federal laws may apply and, under certain circumstances, the laws of the state you live in.

SECTION 2 Notice about nondiscrimination

We don't discriminate based on a person's race, disability, religion, sex, health, ethnicity, creed, age, or national origin. All organizations that provide Medicare Advantage Plans, like our plan, must obey federal laws against discrimination, including Title VI of the Civil Rights Act of 1964, the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, the Americans with Disabilities Act, all other laws that apply to organizations that get federal funding, and any other laws and rules that apply for any other reason.

SECTION 3 Notice about Medicare Secondary Payer subrogation rights

We have the right and responsibility to collect for covered Medicare services for which Medicare is not the primary payer. According to CMS regulations at 42 CFR sections 422.108 and 423.462, Humana Gold Plus H0108-004 (HMO), as a Medicare Advantage Organization, will exercise the same rights of recovery that the Secretary exercises under CMS regulations in subparts B through D of part 411 of 42 CFR and the rules established in this section supersede any State laws.

SECTION 4 Additional Notice about Subrogation and Third Party Recovery

Subrogation

If we make any payment to you or on your behalf for covered services, we are entitled to be fully subrogated to any and all rights you have against any person, entity, or insurer that may be responsible for payment of medical expenses and/or benefits related to your injury, illness, or condition.

Once we have made a payment for covered services, we shall have a lien on the proceeds of any judgment, settlement, or other award or recovery you receive, including but not limited to the following:

1. Any award, settlement, benefits, or other amounts paid under any workers' compensation law or award;
2. Any and all payments made directly by or on behalf of a third-party tortfeasor or person, entity, or insurer responsible for indemnifying the third-party tortfeasor;
3. Any arbitration awards, payments, settlements, structured settlements, or other benefits or amounts paid under an uninsured or underinsured motorist coverage policy; or
4. Any other payments designated, earmarked, or otherwise intended to be paid to you as compensation, restitution, or remuneration for your injury, illness, or condition suffered as a result of the negligence or liability of a third party.

You agree to cooperate with us and any of our representatives and to take any actions or steps necessary to secure our lien, including but not limited to:

1. Responding to requests for information about any accidents or injuries;
2. Responding to our requests for information and providing any relevant information that we have requested; and
3. Participating in all phases of any legal action we commence in order to protect our rights, including, but not limited to, participating in discovery, attending depositions, and appearing and testifying at trial.

In addition, you agree not to do anything to prejudice our rights, including, but not limited to, assigning any rights or causes of action that you may have against any person or entity relating to your injury, illness, or condition without our prior express written consent. Your failure to cooperate shall be deemed a breach of your obligations, and we may institute a legal action against you to protect our rights.

Reimbursement

We are also entitled to be fully reimbursed for any and all benefit payments we make to you or on your behalf that are the responsibility of any person, organization, or insurer. Our right of reimbursement is separate and apart from our subrogation right, and is limited only by the amount of actual benefits paid under our plan. You must immediately pay to us any amounts you recover by judgment, settlement, award, recovery, or otherwise from any liable third party, his or her insurer, to the extent that we paid out or provided benefits for your injury, illness, or condition during your enrollment in our plan.

Antisubrogation rules do not apply

Our subrogation and reimbursement rights shall have first priority, to be paid before any of your other claims are paid. Our subrogation and reimbursement rights will not be affected, reduced, or eliminated by the "made whole" doctrine or any other equitable doctrine.

We are not obligated to pursue subrogation or reimbursement either for our own benefit or on your behalf. Our rights under Medicare law and this Evidence of Coverage shall not be affected, reduced, or eliminated by our failure to intervene in any legal action you commence relating to your injury, illness, or condition.

SECTION 5 Notice of coordination of benefits

Why do we need to know if you have other coverage?

We coordinate benefits in accordance with the Medicare Secondary Payer rules, which allow us to bill, or authorize a provider of services to bill, other insurance carriers, plans, policies, employers, or other entities when the other payer is responsible for payment of services provided to you. We are also authorized to charge or bill you for amounts the other payer has already paid to you for such services. We shall have all the rights accorded to the Medicare Program under the Medicare Secondary Payer rules.

Who pays first when you have other coverage?

When you have additional coverage, how we coordinate your coverage depends on your situation. With coordination of benefits, you will often get your care as usual through our plan providers, and the other plan or plans you have will simply help pay for the care you receive. If you have group health coverage, you may be able to maximize the benefits available to you if you use providers who participate in your group plan **and** our plan. In other situations, such as for benefits that are not covered by our plan, you may get your care outside of our plan.

Employer and employee organization group health plans

Sometimes, a group health plan must provide health benefits to you before we will provide health benefits to you. This happens if:

- You have coverage under a group health plan (including both employer and employee organization plans), either directly or through your spouse, and
- The employer has twenty (20) or more employees (as determined by Medicare rules), and
- You are not covered by Medicare due to disability or End Stage Renal Disease (ESRD).

If the employer has fewer than twenty (20) employees, generally we will provide your primary health benefits. If you have retiree coverage under a group health plan, either directly or through your spouse, generally we will provide primary health benefits. Special rules apply if you have or develop ESRD.

Employer and employee organization group health plans for people who are disabled

If you have coverage under a group health plan, and you have Medicare because you are disabled, generally we will provide your primary health benefits. This happens if:

- You are under age 65, and
- You do not have ESRD, and
- You do not have coverage directly or through your spouse under a large group health plan.

A large group health plan is a health plan offered by an employer with 100 or more employees, or by an employer who is part of a multiple-employer plan where any employer participating in the plan has 100 or more employees. If you have coverage under a large group health plan, either directly or through your spouse, your large group health plan must provide health benefits to you before we will provide health benefits to you. This happens if:

- You do not have ESRD, and
- Are under age 65 and have Medicare based on a disability.

In such cases, we will provide only those benefits not covered by your large employer group plan. Special rules apply if you have or develop ESRD.

Employer and employee organization group health plans for people with End Stage Renal Disease ("ESRD")

If you are or become eligible for Medicare because of ESRD and have coverage under an employer or employee organization group health plan, either directly or through your spouse, your group health plan is responsible for providing primary health benefits to you for the first thirty (30) months after you become eligible for Medicare due to your ESRD. We will provide secondary coverage to you during this time, and we will provide primary coverage to you thereafter. If you are already on Medicare because of age or disability when you develop ESRD, we will provide primary coverage.

Workers' Compensation and similar programs

If you have suffered a job-related illness or injury and workers' compensation benefits are available to you, workers' compensation must provide its benefits first for any healthcare costs related to your job-related illness or injury before we will provide any benefits under this Evidence of Coverage for services rendered in connection with your job-related illness or injury.

Accidents and injuries

The Medicare Secondary Payer rules apply if you have been in an accident or suffered an injury. If benefits under "Med Pay," no-fault, automobile, accident, or liability coverage are available to you, the "Med Pay," no-fault, automobile, accident, or liability coverage carrier must provide its benefits first for any healthcare costs related to the accident or injury before we will provide any benefits for services related to your accident or injury.

Liability insurance claims are often not settled promptly. We may make conditional payments while the liability claim is pending. We may also receive a claim and not know that a liability or other claim is pending. In these situations, our payments are conditional. Conditional payments must be refunded to us upon receipt of the insurance or liability payment.

If you recover from a third party for medical expenses, we are entitled to recovery of payments we have made without regard to any settlement agreement stipulations. Stipulations that the settlement does not include damages for medical expenses will be disregarded. We will recognize allocations of liability payments to non-medical losses only when payment is based on a court order on the merits of the case. We will not seek recovery from any portion of an award that is appropriately designated by the court as payment for losses other than medical services (e.g., property losses).

Where we provide benefits in the form of services, we shall be entitled to reimbursement on the basis of the reasonable value of the benefits provided.

Non-duplication of benefits

We will not duplicate any benefits or payments you receive under any automobile, accident, liability, or other coverage. You agree to notify us when such coverage is available to you, and it is your responsibility to take any actions necessary to receive benefits or payments under such automobile, accident, liability, or other coverage. We may seek reimbursement of the reasonable value of any benefits we have provided in the event that we have duplicated benefits to which you are entitled under such coverage. You are obligated to cooperate with us in obtaining payment from any automobile, accident, or liability coverage or other carrier.

If we do provide benefits to you before any other type of health coverage you may have, we may seek recovery of those benefits in accordance with the Medicare Secondary Payer rules. Please also refer to the **Subrogation and third-party recovery** section for more information on our recovery rights.

More information

This is just a brief summary. Whether we pay first or second - or at all - depends on what types of additional insurance you have and the Medicare rules that apply to your situation. For more information, consult the brochure published by the government called "Medicare and Other Health Benefits: Your Guide to WHO PAYS FIRST." It is CMS Pub. No. 02179. Be sure to consult the most current version. Other details are explained in the Medicare Secondary Payer rules, such as the way the number of persons employed by an employer for purposes of the coordination of benefits rules is to be determined. The rules are published in the Code of Federal Regulations.

Appeal rights

If you disagree with any decision or action by our plan in connection with the coordination of benefits and payment rules outlined above, you must follow the procedures explained in Chapter 9 What to do if you have a problem or complaint (coverage decisions, appeals, complaints) in this Evidence of Coverage.

Chapter 12. Definitions of important words

Advanced Imaging Services - Computed Tomography Imaging (CT/CAT) Scan, Magnetic Resonance Angiography (MRA), Magnetic Resonance Imaging (MRI), and Positron Emission Tomography (PET) Scan.

Allowed Amount - Individual charge determined by a carrier for a covered medical service or supply.

Ambulatory Surgical Center - An Ambulatory Surgical Center is an entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients not requiring hospitalization and whose expected stay in the center does not exceed 24 hours.

Annual Enrollment Period - A set time each fall when members can change their health or drugs plans or switch to Original Medicare. The Annual Enrollment Period is from October 15 until December 7.

Appeal - An appeal is something you do if you disagree with our decision to deny a request for coverage of health care services or prescription drugs or payment for services or drugs you already received. You may also make an appeal if you disagree with our decision to stop services that you are receiving. For example, you may ask for an appeal if we don't pay for a drug, item, or service you think you should be able to receive. Chapter 9 explains appeals, including the process involved in making an appeal.

Balance Billing - When a provider (such as a doctor or hospital) bills a patient more than the plan's allowed cost-sharing amount. As a member of Humana Gold Plus H0108-004 (HMO), you only have to pay our plan's cost-sharing amounts when you get services covered by our plan. We do not allow providers to "balance bill" or otherwise charge you more than the amount of cost sharing your plan says you must pay.

Benefit Period - The way that Original Medicare measures your use of hospital and skilled nursing facility (SNF) services. For our plan, you will have a benefit period for your skilled nursing facility benefits. A benefit period begins the day you go into a skilled nursing facility. The benefit period will accumulate one day for each day you are inpatient at a SNF. The benefit period ends when you haven't received any inpatient skilled care in a SNF for 60 days in a row. If you go into a skilled nursing facility after one benefit period has ended, a new benefit period begins. There is no limit to the number of benefit periods.

Brand-Name Drug - A prescription drug that is manufactured and sold by the pharmaceutical company that originally researched and developed the drug. Brand-name drugs have the same active-ingredient formula as the generic version of the drug. However, generic drugs are manufactured and sold by other drug manufacturers and are generally not available until after the patent on the brand-name drug has expired.

Catastrophic Coverage Stage - The stage in the Part D Drug Benefit where you pay a low copayment or coinsurance for your drugs after you or other qualified parties on your behalf have spent **\$4,550** in covered drugs during the covered year.

Centers for Medicare & Medicaid Services (CMS) - The federal agency that administers Medicare. Chapter 2 explains how to contact CMS.

Coinsurance - An amount you may be required to pay as your share of the cost for services or prescription drugs after you pay any deductibles. Coinsurance is usually a percentage (for example, **20 percent**).

Comprehensive Outpatient Rehabilitation Facility (CORF) - A facility that mainly provides rehabilitation services after an illness or injury, and provides a variety of services including physical therapy, social or psychological services, respiratory therapy, occupational therapy and speech-language pathology services, and home environment evaluation services.

Computed Tomography Imaging (CT/CAT) Scan - Combines the use of a digital computer together with a rotating X-ray device to create detailed cross-sectional images of different organs and body parts.

Contracted Rate - The rate the network provider or pharmacy has agreed to accept for covered services or prescription drugs.

Copayment - An amount you may be required to pay as your share of the cost for a medical service or supply, like a doctor's visit, hospital outpatient visit, or a prescription drug. A copayment is usually a set amount, rather than a percentage. For example, you might pay **\$10** or **\$20** for a doctor's visit or prescription drug.

Cost Sharing - Cost sharing refers to amounts that a member has to pay when services or drugs are received. Cost sharing includes any combination of the following three types of payments: (1) any "deductible" amount a plan may impose before services or drugs are covered; (2) any fixed "copayment" amount that a plan requires when a specific service or drug is received; or (3) any "coinsurance" amount, a percentage of the total amount paid for a service or drug, that a plan requires when a specific service or drug is received. A "daily cost-sharing rate" may apply when your doctor prescribes less than a full month's supply of certain drugs for you and you are required to pay a copayment.

Cost-Sharing Tier - Every drug on the list of covered drugs is in one of five cost-sharing tiers. In general, the higher the cost-sharing tier, the higher your cost for the drug.

Coverage Determination - A decision about whether a drug prescribed for you is covered by the plan and the amount, if any, you are required to pay for the prescription. In general, if you bring your prescription to a pharmacy and the pharmacy tells you the prescription isn't covered under your plan, that isn't a coverage determination. You need to call or write to your plan to ask for a formal decision about the coverage. Coverage determinations are called "coverage decisions" in this booklet. Chapter 9 explains how to ask us for a coverage decision.

Covered Drugs - The term we use to mean all of the prescription drugs covered by our plan.

Covered Services - The general term we use to mean all of the health care services and supplies that are covered by our plan.

Creditable Prescription Drug Coverage - Prescription drug coverage (for example, from an employer or union) that is expected to pay, on average, at least as much as Medicare's standard prescription drug coverage. People who have this kind of coverage when they become eligible for Medicare can generally keep that coverage without paying a penalty, if they decide to enroll in Medicare prescription drug coverage later.

Custodial Care - Custodial care is personal care provided in a nursing home, hospice, or other facility setting when you do not need skilled medical care or skilled nursing care. Custodial care is personal care that can be provided by people who don't have professional skills or training, such as help with activities of daily living like bathing, dressing, eating, getting in or out of a bed or chair, moving around, and using the bathroom. It may also include the kind of health-related care that most people do themselves, like using eye drops. Medicare doesn't pay for custodial care.

Customer Care - A department within our plan responsible for answering your questions about your membership, benefits, grievances, and appeals. See Chapter 2 for information about how to contact Customer Care.

Daily cost-sharing rate - A "daily cost-sharing rate" may apply when your doctor prescribes less than a full month's supply of certain drugs for you and you are required to pay a copayment. A daily cost sharing rate is the copay divided by the number of days in a month's supply. Here is an example: If your copay for a one-month supply of a drug is \$30, and a one-month's supply in your plan is 30 days, then your "daily cost-sharing rate" is \$1 per day. This means you pay \$1 for each day's supply when you fill your prescription.

Deductible - The amount you must pay for health care or prescriptions before our plan begins to pay.

Diagnostic Mammogram - A radiological procedure furnished to a man or woman with signs or symptoms of breast disease.

Disenroll or Disenrollment - The process of ending your membership in our plan. Disenrollment may be voluntary (your own choice) or involuntary (not your own choice).

Dispensing Fee - A fee charged each time a covered drug is dispensed to pay for the cost of filling a prescription. The dispensing fee covers costs such as the pharmacist's time to prepare and package the prescription.

Durable Medical Equipment - Certain medical equipment that is ordered by your doctor for medical reasons. Examples are walkers, wheelchairs, or hospital beds.

Emergency - A medical emergency is when you, or any other prudent layperson with an average knowledge of health and medicine, believe that you have medical symptoms that require immediate medical attention to prevent loss of life, loss of a limb, or loss of function of a limb. The medical symptoms may be an illness, injury, severe pain, or a medical condition that is quickly getting worse.

Emergency Care - Covered services that are: (1) rendered by a provider qualified to furnish emergency services; and (2) needed to treat, evaluate, or stabilize an emergency medical condition.

Evidence of Coverage (EOC) and Disclosure Information - This document, along with your enrollment form and any other attachments, riders, or other optional coverage selected, which explains your coverage, what we must do, your rights, and what you have to do as a member of our plan.

Exception - A type of coverage determination that, if approved, allows you to get a drug that is not on your plan sponsor's formulary (a formulary exception), or get a non-preferred drug at the preferred cost-sharing level (a tiering exception). You may also request an exception if your plan sponsor requires you to try another drug before receiving the drug you are requesting, or the plan limits the quantity or dosage of the drug you are requesting (a formulary exception).

Extra Help - A Medicare program to help people with limited income and resources pay Medicare prescription drug program costs, such as premiums, deductibles, and coinsurance.

Formulary - A list of covered drugs provided by the plan.

Freestanding Dialysis Center - A freestanding facility that provides dialysis on an outpatient basis. This type of facility does not provide inpatient room and board and is Medicare-certified and licensed by the proper authority.

Freestanding Lab - A freestanding facility that provides laboratory tests on an outpatient basis for the prevention, diagnosis, and treatment of an injury or illness. This type of facility does not provide inpatient room and board and is Medicare-certified and licensed by the proper authority.

Freestanding Radiology (Imaging) Center - A freestanding facility that provides one or more of the following services on an outpatient basis for the prevention, diagnosis, and treatment of an injury or illness: X-rays; nuclear medicine; radiation oncology. This type of facility does not provide inpatient room and board and is Medicare-certified and licensed by the proper authority.

Generic Drug - A prescription drug that is approved by the Food and Drug Administration (FDA) as having the same active ingredient(s) as the brand-name drug. Generally, a “generic” drug works the same as a brand-name drug and usually costs less.

Grievance - A type of complaint you make about us or one of our network providers or pharmacies, including a complaint concerning the quality of your care. This type of complaint does not involve coverage or payment disputes.

Health Maintenance Organization (HMO) - A type of Medicare managed care plan where a group of doctors, hospitals, and other health care providers agree to give health care to Medicare beneficiaries for a set amount of money from Medicare every month. You usually must get your care from the providers in the plan.

Home Health Aide - A home health aide provides services that don't need the skills of a licensed nurse or therapist, such as help with personal care (e.g., bathing, using the toilet, dressing, or carrying out the prescribed exercises). Home health aides do not have a nursing license or provide therapy.

Home Health Care - Skilled nursing care and certain other health care services that you get in your home for the treatment of an illness or injury. Covered services are listed in Chapter 4 under the heading, “Home health care.” If you need home health care services, our plan will cover these services for you, provided the Medicare coverage requirements are met. Home health care can include services from a home health aide if the services are part of the home health plan of care for your illness or injury. They aren't covered unless you are also getting a covered skilled service. Home health services don't include the services of housekeepers, food service arrangements, or full-time nursing care at home.

Hospice Care - A special way of caring for people who are terminally ill and providing counseling for their families. Hospice care is physical care and counseling that is given by a team of people who are part of a Medicare-certified public agency or private company. Depending on the situation, this care may be given in the home, a hospice facility, a hospital, or a nursing home. Care from a hospice is meant to help patients in the last months of life by giving comfort and relief from pain. The focus is on care, not cure. For more information on hospice care, visit www.medicare.gov and under “Search Tools” choose “Find a Medicare Publication” to view or download the publication “Medicare Hospice Benefits.” Or, call 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Hospital Inpatient Stay - A hospital stay when you have been formally admitted to the hospital for skilled medical services. Even if you stay in the hospital overnight, you might still be considered an “outpatient.”

Humana's National Transplant Network (NTN) - A network of Humana-approved facilities all of which are also Medicare-approved facilities.

Immediate Care Facility - A facility established to diagnose and treat an unforeseen injury or illness on an outpatient basis. This facility is staffed by physicians and provides treatment by, or under, the supervision of physicians as well as nursing care. This type of facility does not provide inpatient room and board.

Initial Coverage Limit - The maximum limit of coverage under the Initial Coverage Stage.

Initial Coverage Stage - This is the stage before your total drug expenses have reached **\$2,850**, including amounts you've paid and what our plan has paid on your behalf.

Initial Enrollment Period - When you are first eligible for Medicare, the period of time when you can sign up for Medicare Part A and Part B. For example, if you're eligible for Medicare when you turn 65, your Initial Enrollment Period is the 7-month period that begins 3 months before the month you turn 65, includes the month you turn 65, and ends 3 months after the month you turn 65.

Inpatient Care - Health care that you get when you are admitted to a hospital.

Institutional Equivalent Special Needs Plan (SNP) - An institutional Special Needs Plan that enrolls eligible individuals living in the community but requiring an institutional level of care based on the State assessment. The assessment must be performed using the same respective State level of care assessment tool and administered by an entity other than the organization offering the plan. This type of Special Needs Plan may restrict enrollment to individuals that reside in a contracted assisted living facility (ALF) if necessary to ensure uniform delivery of specialized care.

Institutional Special Needs Plan (SNP) - A Special Needs Plan that enrolls eligible individuals who continuously reside or are expected to continuously reside for 90 days or longer in a long-term care (LTC) facility. These LTC facilities may include a skilled nursing facility (SNF); nursing facility (NF); (SNF/NF); an intermediate care facility for the mentally retarded (ICF/MR); and/or an inpatient psychiatric facility. An institutional Special Needs Plan to serve Medicare residents of LTC facilities must have a contractual arrangement with (or own and operate) the specific LTC facility (ies).

Late Enrollment Penalty - An amount added to your monthly premium for Medicare drug coverage if you go without creditable coverage (coverage that is expected to pay, on average, at least as much as standard Medicare prescription drug coverage) for a continuous period of 63 days or more. You pay this higher amount as long as you have a Medicare drug plan. There are some exceptions. For example, if you receive "Extra Help" from Medicare to pay your prescription drug plan costs, the late enrollment penalty rules do not apply to you. If you receive "Extra Help", you do not pay a penalty, even if you go without "creditable" prescription drug coverage.

List of Covered Drugs (Formulary or "Drug Guide") - A list of prescription drugs covered by the plan. The drugs on this list are selected by the plan with the help of doctors and pharmacists. The list includes both brand-name and generic drugs.

Low Income Subsidy (LIS) - See "Extra Help."

Magnetic Resonance Angiography (MRA) - A noninvasive method and a form of magnetic resonance imaging (MRI) that can measure blood flow through blood vessels.

Magnetic Resonance Imaging (MRI) - A diagnostic imaging modality method that uses a magnetic field and computerized analysis of induced radio frequency signals to noninvasively image body tissue.

Medicaid (or Medical Assistance) - A joint federal and state program that helps with medical costs for some people with low incomes and limited resources. Medicaid programs vary from state to state, but most health care costs are covered if you qualify for both Medicare and Medicaid. See Chapter 2, Section 6 for information about how to contact Medicaid in your state.

Medically Accepted Indication - A use of a drug that is either approved by the Food and Drug Administration or supported by certain reference books. See Chapter 5, Section 3 for more information about a medically accepted indication.

Medically Necessary - Services, supplies, or drugs that are needed for the prevention, diagnosis, or treatment of your medical condition and meet accepted standards of medical practice.

Medicare - The federal health insurance program for people 65 years of age or older, some people under age 65 with certain disabilities, and people with End-Stage Renal Disease (generally those with permanent kidney failure who need dialysis or a kidney transplant). People with Medicare can get their Medicare health coverage through Original Medicare, a PACE plan, or a Medicare Advantage Plan.

Medicare Advantage Disenrollment Period - A set time each year when members in a Medicare Advantage Plan can cancel their plan enrollment and switch to Original Medicare. The Medicare Advantage Disenrollment Period is from January 1 until February 14, 2014.

Medicare Advantage Organization - Medicare Advantage Plans are run by private companies. They give you more options, and sometimes, extra benefits. These plans are still part of the Medicare program and are also called “Part C.” They provide all your Part A (Hospital) and Part B (Medical) coverage. Some may also provide Part D (Prescription Drug) coverage.

Medicare Advantage (MA) Plan - Sometimes called Medicare Part C. A plan offered by a private company that contracts with Medicare to provide you with all your Medicare Part A and Part B benefits. A Medicare Advantage Plan can be an HMO, PPO, a Private Fee-for-Service (PFFS) plan, or a Medicare Medical Savings Account (MSA) plan. When you are enrolled in a Medicare Advantage Plan, Medicare services are covered through the plan, and are not paid for under Original Medicare. In most cases, Medicare Advantage Plans also offer Medicare Part D (prescription drug coverage). These plans are called **Medicare Advantage Plans with Prescription Drug Coverage**. Everyone who has Medicare Part A and Part B is eligible to join any Medicare health plan that is offered in their area, except people with End-Stage Renal Disease (unless certain exceptions apply).

Medicare Allowable Charge - The amount allowed by Medicare for a particular benefit or service.

Medicare Coverage Gap Discount Program - A program that provides discounts on most covered Part D brand-name drugs to Part D enrollees who have reached the Coverage Gap Stage and who are not already receiving “Extra Help.” Discounts are based on agreements between the federal government and certain drug manufacturers. For this reason, most, but not all, brand-name drugs are discounted.

Medicare-Covered Services - Services covered by Medicare Part A and Part B. All Medicare health plans, including our plan, must cover all of the services that are covered by Medicare Part A and B.

Medicare Health Plan - A Medicare health plan is offered by a private company that contracts with Medicare to provide Part A and Part B benefits to people with Medicare who enroll in the plan. This term includes all Medicare Advantage Plans, Medicare Cost Plans, Demonstration/Pilot Programs, and Programs of All-inclusive Care for the Elderly (PACE).

Medicare Limiting Charge - In the Original Medicare plan, the highest amount of money you can be charged for a covered service by doctors and other health care suppliers who do not accept assignment. The limiting charge is 15 percent over Medicare's approved amount. The limiting charge only applies to certain services and does not apply to supplies or equipment.

Medicare Prescription Drug Coverage (Medicare Part D) - Insurance to help pay for outpatient prescription drugs, vaccines, biologicals, and some supplies not covered by Medicare Part A or Part B.

"Medigap" (Medicare Supplement Insurance) Policy - Medicare supplement insurance sold by private insurance companies to fill "gaps" in Original Medicare. Medigap policies only work with Original Medicare. (A Medicare Advantage Plan is not a Medigap policy.)

Member (Member of our Plan, or "Plan Member") - A person with Medicare who is eligible to get covered services, who has enrolled in our plan and whose enrollment has been confirmed by the Centers for Medicare & Medicaid Services (CMS).

Network Pharmacy - A network pharmacy is a pharmacy where members of our plan can get their prescription drug benefits. We call them "network pharmacies" because they contract with our plan. In most cases, your prescriptions are covered only if they are filled at one of our network pharmacies.

Network Provider - "Provider" is the general term we use for doctors, other health care professionals, hospitals, and other health care facilities that are licensed or certified by Medicare and by the state to provide health care services. We call them "**network providers**" when they have an agreement with our plan to accept our payment as payment in full, and in some cases to coordinate as well as provide covered services to members of our plan. Our plan pays network providers based on the agreements it has with the providers or if the providers agree to provide you with plan-covered services. Network providers may also be referred to as "plan providers."

Non-Plan Provider or Non-Plan Facility - A provider or facility with which we have not arranged to coordinate or provide covered services to members of our plan. Non-plan providers are providers that are not employed, owned, or operated by our plan or are not under contract to deliver covered services to you. As explained in this booklet, most services you get from non-plan providers are not covered by our plan or Original Medicare.

Non-Preferred Network Pharmacy - A network pharmacy that offers covered drugs to members of our plan at higher cost-sharing levels than apply at a preferred network pharmacy.

Nuclear Medicine - Radiology in which radioisotopes (compounds containing radioactive forms of atoms) are introduced into the body for the purpose of imaging, evaluating organ function, or localizing disease or tumors.

Observation - A stay in a hospital for less than 24 hours if: (1) You have not been admitted as a registered bed patient; (2) you are physically detained in an emergency room, treatment room, observation room, or other such area; or (3) you are being observed to determine whether an inpatient confinement will be required.

Optional Supplemental Benefits - Non-Medicare-covered benefits that can be purchased for an additional premium and are not included in your package of benefits. If you choose to have optional supplemental benefits, you may have to pay an additional premium. You must voluntarily elect Optional Supplemental Benefits in order to get them.

Organization Determination - The Medicare Advantage plan has made an organization determination when it makes a decision about whether items or services are covered or how much you have to pay for covered items or services. The Medicare Advantage plan's network provider or facility has also made an organization determination when it provides you with an item or service, or refers you to an out-of-network provider for an item or service. Organization determinations are called "coverage decisions" in this booklet. Chapter 9 explains how to ask us for a coverage decision.

Original Medicare ("Traditional Medicare" or "Fee-for-service" Medicare) - Original Medicare is offered by the government, and not a private health plan such as Medicare Advantage Plans and prescription drug plans. Under Original Medicare, Medicare services are covered by paying doctors, hospitals, and other health care providers payment amounts established by Congress. You can see any doctor, hospital, or other health care provider that accepts Medicare. You must pay the deductible. Medicare pays its share of the Medicare-approved amount, and you pay your share. Original Medicare has two parts: Part A (Hospital Insurance) and Part B (Medical Insurance) and is available everywhere in the United States.

Our plan - The plan you are enrolled in, Humana Gold Plus H0108-004 (HMO)

Out-of-Network Pharmacy - A pharmacy that doesn't have a contract with our plan to coordinate or provide covered drugs to members of our plan. As explained in this Evidence of Coverage, most drugs you get from out-of-network pharmacies are not covered by our plan unless certain conditions apply.

Out-of-Network Provider or Out-of-Network Facility - A provider or facility with which we have not arranged to coordinate or provide covered services to members of our plan. Out-of-network providers are providers that are not employed, owned, or operated by our plan or are not under contract to deliver covered services to you. Using out-of-network providers or facilities is explained in this booklet in Chapter 3.

Out-of-Pocket Costs - See the definition for "cost sharing" above. A member's cost-sharing requirement to pay for a portion of services or drugs received is also referred to as the member's "out-of-pocket" cost requirement.

PACE plan - A PACE (Program of All-inclusive Care for the Elderly) plan combines medical, social, and long-term care services for frail people to help people stay independent and living in their community (instead of moving to a nursing home) as long as possible, while getting the high-quality care they need. People enrolled in PACE plans receive both their Medicare and Medicaid benefits through the plan.

Part C - see "Medicare Advantage (MA) Plan."

Part D - The voluntary Medicare Prescription Drug Benefit Program. (For ease of reference, we will refer to the prescription drug benefit program as Part D.)

Part D Drugs - Drugs that can be covered under Part D. We may or may not offer all Part D drugs. (See your formulary for a specific list of covered drugs.) Certain categories of drugs were specifically excluded by Congress from being covered as Part D drugs.

Plan Provider – see "Network Provider".

Point-of-Service (POS) Plan - A Medicare managed care plan option that lets you use doctors and hospitals outside the plan for an additional cost.

Positron Emission Tomography (PET) Scan - A medical imaging technique that involves injecting the patient with an isotope and using a PET scanner to detect the radiation emitted.

Preferred Network Pharmacy - A network pharmacy that offers covered drugs to members of our plan that may have lower cost-sharing levels than at other network pharmacies.

Preferred Provider Organization (PPO) Plan - A Preferred Provider Organization plan is a Medicare Advantage Plan that has a network of contracted providers that have agreed to treat plan members for a specified payment amount. A PPO plan must cover all plan benefits whether they are received from network or out-of-network providers. Member cost sharing will generally be higher when plan benefits are received from out-of-network providers. PPO plans have an annual limit on your out-of-pocket costs for services received from network (preferred) providers and a higher limit on your total combined out-of-pocket costs for services from both in-network (preferred) and out-of-network (non-preferred) providers.

Premium - The periodic payment to Medicare, an insurance company, or a health care plan for health or prescription drug coverage.

Prescription Drug Guide (Formulary) - A list of covered drugs provided by the plan. The drugs on this list are selected by the plan with the help of doctors and pharmacists. The list includes both brand-name and generic drugs.

Primary Care Physician (PCP) - Your primary care physician is the doctor or other provider you see first for most health problems. He or she makes sure you get the care you need to keep you healthy. He or she also may talk with other doctors and health care providers about your care and refer you to them. In many Medicare health plans, you must see your primary care physician before you see any other health care provider. See Chapter 3, Section 2.1 for information about Primary Care Physicians.

Prior Authorization - Approval in advance to get services or certain drugs that may or may not be on our formulary. Some medical services are covered only if your doctor or other provider gets "prior authorization" from our plan. Covered services that need prior authorization are marked in the Benefits Chart in Chapter 4. Some drugs are covered only if your doctor or other network provider gets "prior authorization" from us. Covered drugs that need prior authorization are marked in the formulary.

Quality Improvement Organization (QIO) - A group of practicing doctors and other health care experts paid by the federal government to check and improve the care given to Medicare patients. See Chapter 2, Section 4 for information about how to contact the QIO in your state.

Quantity Limits - A management tool that is designed to limit the use of selected drugs for quality, safety, or utilization reasons. Limits may be on the amount of the drug that we cover per prescription or for a defined period of time.

Rehabilitation Services - These services include physical therapy, speech and language therapy, and occupational therapy.

Screening Mammogram - A radiological procedure for early detection of breast cancer, and; includes a physician's interpretation of the results.

Service Area - A geographic area where a health plan accepts members if it limits membership based on where people live. For plans that limit which doctors and hospitals you may use, it's also generally the area where you can get routine (non-emergency) services. The plan may disenroll you if you permanently move out of the plan's service area.

Skilled Nursing Facility (SNF) Care - Skilled nursing care and rehabilitation services provided on a continuous, daily basis, in a skilled nursing facility. Examples of skilled nursing facility care include physical therapy or intravenous injections that can only be given by a registered nurse or doctor.

Special Enrollment Period - A set time when members can change their health or drugs plans or return to Original Medicare. Situations in which you may be eligible for a Special Enrollment Period include: if you move outside the service area, if you are getting “Extra Help” with your prescription drug costs, if you move into a nursing home, or if we violate our contract with you.

Special Needs Plan - A special type of Medicare Advantage Plan that provides more focused health care for specific groups of people, such as those who have both Medicare and Medicaid, who reside in a nursing home, or who have certain chronic medical conditions.

Step Therapy - A utilization tool that requires you to first try another drug to treat your medical condition before we will cover the drug your physician may have initially prescribed.

Supplemental Security Income (SSI) - A monthly benefit paid by Social Security to people with limited income and resources who are disabled, blind, or age 65 and older. SSI benefits are not the same as Social Security benefits.

Urgently Needed Care - Urgently needed care is care provided to treat a non-emergency, unforeseen medical illness, injury, or condition that requires immediate medical care. Urgently needed care may be furnished by network providers or by out-of-network providers when network providers are temporarily unavailable or inaccessible.

State Agency Contact Information

This section provides the contact information for the state agencies referenced in Chapter 2 and in other locations within this Evidence of Coverage. If you have trouble locating the information you seek, please contact Customer Care at the phone number on the back cover of this booklet.

State	California
SHIP Name and Contact Information	California Health Insurance Counseling & Advocacy Program (HICAP) 1300 National Drive Suite 200 Sacramento, CA 95834-1992 1-800-434-0222 (toll free) 1-916-419-7500 1-916-928-2267 (fax) 1-800-735-2929 http://www.aging.ca.gov/HICAP/
Quality Improvement Organization	Health Services Advisory Group 700 N. Brand Blvd Suite 370 Glendale, CA 91203 1-866-800-8749 (medicare helpline) 818-409-9229 (local) 1-818-409-0835 (fax) 1-800-881-5980 (TTY) http://www.hsag.com/
State Medicaid Office	Department of Health Care Services - Medi-Cal (Medicaid) PO Box 13029 Sacramento, CA 95813-4029 1-800-541-5555 (toll free) 1-916-636-1980 (local) http://www.medi-cal.ca.gov/

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#:1462

Multi-language Interpreter Services

English: We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at 1-800-457-4708. Someone who speaks English/Language can help you. This is a free service.

Spanish: Tenemos servicios de intérprete sin costo alguno para responder cualquier pregunta que pueda tener sobre nuestro plan de salud o medicamentos. Para hablar con un intérprete, por favor llame al 1-800-457-4708. Alguien que hable español le podrá ayudar. Este es un servicio gratuito.

Chinese Mandarin: 我们提供免费的翻译服务，帮助您解答关于健康或药物保险的任何疑问。如果您需要此翻译服务，请致电 1-800-457-4708。我们的中文工作人员很乐意帮助您。这是一项免费服务。

Chinese Cantonese: 您對我們的健康或藥物保險可能存有疑問，為此我們提供免費的翻譯服務。如需翻譯服務，請致電 1-800-457-4708。我們講中文的人員將樂意為您提供幫助。這是一項免費服務。

Tagalog: Mayroon kaming libreng serbisyo sa pagsasaling-wika upang masagot ang anumang mga katanungan ninyo hinggil sa aming planong pangkalusugan o panggamot. Upang makakuha ng tagasaling-wika, tawagan lamang kami sa 1-800-457-4708. Maaari kayong tulungan ng isang nakakapagsalita ng Tagalog. Ito ay libreng serbisyo.

French: Nous proposons des services gratuits d'interprétation pour répondre à toutes vos questions relatives à notre régime de santé ou d'assurance-médicaments. Pour accéder au service d'interprétation, il vous suffit de nous appeler au 1-800-457-4708. Un interlocuteur parlant Français pourra vous aider. Ce service est gratuit.

Vietnamese: Chúng tôi có dịch vụ thông dịch miễn phí để trả lời các câu hỏi về chương sức khỏe và chương trình thuốc men. Nếu quý vị cần thông dịch viên xin gọi 1-800-281-6918 sẽ có nhân viên nói tiếng Việt giúp đỡ quý vị. Đây là dịch vụ miễn phí.

German: Unser kostenloser Dolmetscherservice beantwortet Ihren Fragen zu unserem Gesundheits- und Arzneimittelpflichtplan. Unsere Dolmetscher erreichen Sie unter 1-800-457-4708. Man wird Ihnen dort auf Deutsch weiterhelfen. Dieser Service ist kostenlos.

Korean: 당사는 의료 보험 또는 약품 보험에 관한 질문에 대해 드리고자 무료 통역 서비스를 제공하고 있습니다. 통역 서비스를 이용하려면 전화 1-800-457-4708 번으로 문의해 주십시오. 한국어를 하는 담당자가 도와 드릴 것입니다. 이 서비스는 무료로 운영됩니다.

Russian: Если у вас возникнут вопросы относительно страхового или медикаментного плана, вы можете воспользоваться нашими бесплатными услугами переводчиков. Чтобы воспользоваться услугами переводчика, позвоните нам по телефону 1-800-457-4708. Вам окажет помощь сотрудник, который говорит по-русски. Данная услуга бесплатная.

Arabic:

إننا نقدم خدمات الترجمة الفورية المجانية للإجابة عن أي أسئلة تتعلق بالصحة أو جدول الأدوية لدينا. للحصول على مترجم فوري، ليس عليك سوى الإتصال بنا على 1-800-457-4708. سيقوم شخص ما يتحدث اللغة العربية بمساعدتك. هذه الخدمة مجانية.

Hindi: हमारे स्वास्थ्य या दवा की योजना के बारे में आपके किसी भी प्रश्न के जवाब देने के लिए हमारे पास मुफ्त दुभाषिया सेवाएँ उपलब्ध हैं। एक दुभाषिया प्राप्त करने के लिए, बस हमें 1-800-457-4708 पर फोन करें। कोई व्यक्ति जो हिन्दी बोलता है आपकी मदद कर सकता है। यह एक मुफ्त सेवा है।

Italian: È disponibile un servizio di interpretariato gratuito per rispondere a eventuali domande sul nostro piano sanitario e farmaceutico. Per un interprete, contattare il numero 1-800-457-4708. Un nostro incaricato che parla Italianovi fornirà l'assistenza necessaria. È un servizio gratuito.

Português: Dispomos de serviços de interpretação gratuitos para responder a qualquer questão que tenha acerca do nosso plano de saúde ou de medicação. Para obter um intérprete, contacte-nos através do número 1-800-457-4708. Irá encontrar alguém que fale o idioma Português para o ajudar. Este serviço é gratuito.

French Creole: Nou genyen sèvis entèprèt gratis pou reponn tout kesyon ou ta genyen konsènan plan medikal ouwa dwòg nou an. Pou jwenn yon entèprèt, jis rele nou nan 1-800-457-4708. Yon moun ki pale Kreyòl kapab ede w. Sa a se yon sèvis ki gratis.

Polish: Umożliwiamy bezpłatne skorzystanie z usług tłumacza ustnego, który pomoże w uzyskaniu odpowiedzi na temat planu zdrowotnego lub dawkowania leków. Aby skorzystać z pomocy tłumacza znającego język polski, należy zadzwonić pod numer 1-800-457-4708. Ta usługa jest bezpłatna.

Japanese: 当社の健康 健康保険と薬品 処方薬プランに関するご質問にお答えするために、無料の通訳サービスがあります。通訳をご用命になるには、1-800-457-4708にお電話ください。日本語を話す人者が支援いたします。これは無料のサービスです。

Humana Gold Plus H0108-004 (HMO) Customer Care

CALL	<p>1-800-457-4708</p> <p>Calls to this number are free. Customer Care is available seven days a week, from 8 a.m. to 8 p.m. (A customer care representative will be available to answer your call directly during the annual enrollment period and 60 days after from 8 a.m. until 8 p.m.)</p> <p>However, beginning February 15, 2014, your call may be handled by our automated phone system on Saturdays, Sundays, and some Public Holidays. When leaving a message, simply select the reason for your call from the automated list and a knowledgeable representative will return your call by the end of the next working day.</p> <p>Customer Care also has free language interpreter services available for non-English speakers.</p>
TTY	<p>711</p> <p>Calls to this number are free. Hours of operation are the same as above.</p> <p>This number requires special telephone equipment and is only for people who have difficulties with hearing or speaking.</p>
FAX	1-877-837-7741
WRITE	Humana, P.O. Box 14168, Lexington, KY 40512-4168
WEBSITE	Humana.com

State Health Insurance Assistance Program

The State Health Insurance Assistance Program (SHIP) is a state program that gets money from the federal government to give free local health insurance counseling to people with Medicare.

Contact information for your State Health Insurance Assistance Program (SHIP) can be found in "Exhibit A" in this document.

Humana Inc.
PO Box 14168
Lexington, KY 40512-4168

Important Plan Information

H0108004EOC14

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Humana.com

A-7441

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

HUMANA INC.,
Plaintiff,

v.

MALLINCKRODT ARD LLC
(f/k/a Mallinckrodt ARD Inc., f/k/a
Questcor Pharmaceuticals, Inc.),
Defendant.

CV 19-6926 DSF (MRWx)

Order GRANTING in Part and
DENYING in Part Defendant's
Motion to Dismiss (Dkt. 65)

Defendant Mallinckrodt ARD LLC moves to dismiss (a) Counts I, II & III (federal and state antitrust laws) in their entirety, or at least to the extent based on any state's antitrust law except Maine, Vermont, or Wisconsin law; (b) Counts IV & V (RICO), Count VI (unfair competition law), Count VII (state consumer fraud and deceptive trade practices acts), and Count VIII (state insurance fraud statutes) to the extent based on allegations regarding co-pay assistance programs; (c) Count IX (tortious interference with contract) in its entirety; and (d) Count VII (state insurance fraud statutes) to the extent asserted under Kentucky or New Jersey law as alleged in Plaintiff Humana Inc.'s Second Amended Complaint (SAC). Dkt. 65-1 (Mot.). Plaintiff opposes. Dkt. 71 (Opp'n). The Court deems this matter appropriate for decision without oral argument. See Fed. R. Civ. P. 78; Local Rule 7-15. For the reasons stated below, the motion is GRANTED in part and DENIED in part.

I. FACTUAL AND PROCEDURAL BACKGROUND

Defendant produces H.P. Acthar Gel (Acthar), a drug that has been available in the United States since it was approved by the FDA in 1952. Dkt. 60 (SAC) ¶¶ 2, 44. Plaintiff operates or administers Medicare Part D plans on behalf of federal and state governments and provides coverage for prescription drugs, including Acthar, through other plans. Id. ¶ 39. Acthar is an adrenocorticotrophic hormone (ACTH) used as an anti-inflammatory. Id. ¶ 41. Acthar is approved to treat exacerbations of multiple sclerosis (MS) as well as other diseases and disorders. Id. ¶ 45. However, for many of these conditions, Acthar is not the “first-line treatment.” Id. ¶ 46. Cheaper, non-ACTH drugs are used to treat the same indications. Id. ¶¶ 49-50, 60. Infantile spasms is the only condition for which Acthar is the “first-line treatment.” Id. ¶ 51 n.4. There is only one other FDA-approved drug for infantile spasms. Id. ¶ 49 n.3. Acthar is the only long-acting ACTH drug approved for sale in the United States. Id. ¶ 61. Another ACTH drug, Synacthen, is approved for sale outside of the United States. Id. ¶ 70. Acthar is not marketed outside of the United States. Id.

Until 2001, when Defendant’s predecessor, Questcor, acquired worldwide rights to sell and manufacture Acthar for \$100,000, plus royalties, Acthar was priced more competitively with other anti-inflammatory drugs. Id. ¶ 47. At that time, because Acthar was expensive to produce and not the first-line treatment for most conditions, the prior manufacturer considered discontinuing production. Id. However, as soon as Questcor acquired the rights to sell Acthar, it increased the price from approximately \$40 per vial to nearly \$750 per vial. Id. ¶ 54. On August 27, 2007, Questcor further increased the price from \$1,650 to \$23,269 per vial. Id. ¶ 55. By 2018, the price had increased to \$38,892. Id. ¶ 56. Between 2011 and 2015, net sales of Acthar increased from \$218 million to more than \$1 billion, and Medicare spending on Acthar increased from \$50 million to \$500 million. Id. ¶¶ 57-58. Humana itself paid for almost \$800 million worth of Acthar since 2001. See id. ¶ 86.

In 2010, Questcor established an MS Acute Exacerbation Fund (MS Fund) with Chronic Disease Fund, Inc. (CDF), a Texas-based charity. Id. ¶¶ 29, 97-98, 108. The MS Fund helped patients with government insurance, such as Medicare, with co-pays for Acthar. Id. ¶ 98. Although the donation agreement stated that the donated funds were generally for the treatment of patients with acute exacerbations of MS, in reality it did not provide co-pay assistance to purchase any other drugs. Id. In 2011, Questcor established a Lupus Exacerbation Fund (Lupus Fund) that was purportedly to provide co-pay assistance for “any medically appropriate therapy,” but in fact was used only to provide assistance for Acthar. Id. ¶ 100. In 2012, Questcor created a similar fund for rheumatoid arthritis (RA Fund). Id. ¶ 101. Between the time Questcor established the MS Fund in 2010 and 2013, Acthar sales for MS treatment nearly quadrupled. Id. ¶ 108.

In late 2012 and early 2013, Novartis, the company that manufactured Synacthen abroad, sought bids from companies who wanted to acquire the rights to seek FDA approval and sell Synacthen in the United States. Id. ¶¶ 73-76. Questcor and three other companies (who were not disclosed) submitted serious bids. Id. The three other companies intended to develop Synacthen to compete with Acthar; Questcor had “inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer.” Id. ¶ 76. However, Questcor’s bid was the highest, at a minimum of \$135 million. Id. ¶¶ 77-78. Neither Questcor nor Defendant “made more than superficial efforts to pursue commercialization of Synacthen . . . to protect Acthar monopoly pricing.” Id. ¶ 81. In July 2017, the FTC approved a sublicense granting another company the rights to develop and market Synacthen to treat infantile spasms and nephrotic syndrome in the United States. Id. ¶ 82.

On March 9, 2020, the Court granted Defendant’s motion to dismiss the antitrust claims and the tortious interference with contractual relations claim in the First Amended Complaint with leave to amend and denied the motion as to the remaining claims. Dkt. 57 (March Order). Defendant again seeks dismissal of the antitrust claims and tortious interference claims in their entirety, as well as

dismissal of the RICO claims, unfair competition claim, state consumer fraud and deceptive practices claims, and insurance fraud claims to the extent they are based on co-pay assistance programs. Defendant additionally seeks dismissal of the insurance fraud claims to the extent they are based on Kentucky or New Jersey law and 22 of the 25 state-law antitrust claims as barred by the statute of limitations.

II. LEGAL STANDARD

Rule 12(b)(6) allows an attack on the pleadings for failure to state a claim on which relief can be granted. “[W]hen ruling on a defendant’s motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint.” Erickson v. Pardus, 551 U.S. 89, 94 (2007) (per curiam). However, a court is “not bound to accept as true a legal conclusion couched as a factual allegation.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). “Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” Id. (quoting Twombly, 550 U.S. at 557) (alteration in original) (citation omitted). A complaint must “state a claim to relief that is plausible on its face.” Twombly, 550 U.S. at 570. This means that the complaint must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Iqbal, 556 U.S. at 678. There must be “sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively . . . and factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation.” Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011).

Ruling on a motion to dismiss is “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not ‘show[n]’ – that the pleader is

entitled to relief.” Iqbal, 556 U.S. at 679 (alteration in original) (citation omitted) (quoting Fed. R. Civ. P. 8(a)(2)).

As a general rule, leave to amend a complaint that has been dismissed should be freely granted. Fed. R. Civ. P. 15(a). However, leave to amend may be denied when “the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency.” Schreiber Distrib. Co. v. Serv-Well Furniture Co., 806 F.2d 1393, 1401 (9th Cir. 1986).

III. DISCUSSION

A. Antitrust Claims (Counts I through III)

Plaintiff alleges that Defendant has monopoly power in the market for “long-acting ACTH drugs in the United States” and that Questcor’s acquisition of the rights to develop and market Synacthen in the United States “restrained trade” in the relevant market and “eliminated [a] potential competitive threat” in order to “maintain its monopoly” so it can “stabilize or raise the price of Acthar to a higher level” and “suppress[] the output of long-acting ACTH drugs below the level of output” that would exist in a competitive market. SAC ¶¶ 140-42, 146-48. This conduct purportedly violates Sections 1 and 2 of the Sherman Antitrust Act and corresponding state antitrust laws.

“In order to state a Section 1 claim . . . plaintiffs must plead facts which, if true, will prove ‘(1) a contract, combination or conspiracy among two or more persons or distinct business entities; (2) by which the persons or entities intended to harm or restrain trade or commerce among the several States, or with foreign nations; (3) which actually injures competition,’” and “(4) that they were harmed by the defendant’s anti-competitive contract, combination, or conspiracy, and that this harm flowed from an ‘anti-competitive aspect of the practice under scrutiny.’” Brantley v. NBC Universal, Inc., 675 F.3d 1192, 1197 (9th Cir. 2012) (first quoting Kendall v. Visa U.S.A., Inc., 518 F.3d 1042, 1046 (9th Cir. 2008); then quoting Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990)). Section 2 “targets ‘the willful acquisition or maintenance of [monopoly] power as distinguished from

growth or development as a consequence of a superior product, business acumen, or historic accident.” Pac. Bell Tel. Co. v. Linkline Commc’ns, Inc., 555 U.S. 438, 448 (2009) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570 (1966)). “Simply possessing monopoly power and charging monopoly prices does not violate § 2.” Id. at 447-48.

1. Market Power

Both Section 1 and Section 2 claims depend on whether Plaintiff has sufficiently alleged Defendant has market power in a relevant antitrust market. Newcal Indus., Inc. v. Ikon Office Sol., 513 F.3d 1038, 1044 n.3 (9th Cir. 2008) (“The ‘relevant market’ and ‘market power’ requirements apply identically under the two different sections of the Act, meaning that the requirements apply identically to” both Section 1 and Section 2 claims and plaintiff’s “market allegations are either sufficient or insufficient for all [antitrust] claims.”). “An antitrust complaint therefore survives a Rule 12(b)(6) motion unless it is apparent from the face of the complaint that the alleged market suffers a fatal legal defect.” Id. at 1045. One such fatal defect is the failure of the alleged market to “encompass . . . all economic substitutes for the product.” Id. The Court previously dismissed Plaintiff’s antitrust claims, in part, for failing to allege a facially sustainable product market definition. March Order at 13.

Plaintiff now alleges that the relevant market is the market for “the sale of long-acting ACTH drugs in the United States.” SAC ¶¶ 140 (Section 2), 147 (Section 1). Plaintiff further alleges that Defendant’s product, Acthar, “represents 100% of th[at] sub-market.” Id. ¶ 60. Defendant contends that “the SAC . . . proposes yet another *even narrower* ACTH-only market that continues to exclude economic substitutes for Acthar described in Humana’s own complaint.” Mot. at 2.¹ This is true in some sense if each allegation is considered in a

¹ Although Defendant emphasizes that the proposed market definition is “even narrower” with the exclusion of short-acting ACTH, Defendant does not appear to dispute that short-acting ACTH drugs are reasonably excluded from the relevant market. See Mot. at 6 (addressing why Plaintiff must

vacuum. In addition to the many paragraphs identified in the March Order that remain materially unchanged, March Order at 6-7 (citing FAC ¶¶ 6, 13, 43, 46, 49, 57, 84, 147, 151), Plaintiff’s amended complaint adds allegations that appear to contradict its proposed market, see, e.g., SAC ¶¶ 49-50 (“prednisone is approved by the FDA to treat all of the same diseases and disorders as Acthar” and “Acthar has similar pharmacodynamic effects as corticosteroids”); id. ¶ 49 (“Acthar has been compared to intravenous methylprednisolone for treatment of MS relapses and to prednisone for treatment of sarcoidosis”). However, Plaintiff has also added allegations in support of its claim that there is a “long-acting ACTH drug[] . . . submarket within a broader market for adrenal hormone drugs.” Id. ¶ 89. And within these allegations, the Court concludes that Plaintiff has adequately alleged a long-acting ACTH submarket.

“To plead an antitrust claim based on a submarket, ‘the plaintiff must be able to show (but need not necessarily establish in the complaint) that the alleged submarket is economically distinct from the general product market.’” Hicks v. PGA Tour, Inc., 897 F.3d 1109, 1121 (9th Cir. 2018) (quoting Newcal Indus., Inc. v. Ikon Office Sol., 513 F.3d 1038, 1045 (9th Cir. 2008)). A plaintiff can do so by alleging “industry or public recognition of the submarket as a separate economic entity, the product’s peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.” Id. (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962)).

allege indication-based markets and acknowledging Plaintiff’s allegation that “short-acting ACTH drugs are not included in the relevant market ‘because there is no overlap in the medical conditions that the drugs are approved to treat or diagnose’” (citing SAC ¶ 52 n.6)); id. at 11-12 (“Only for those indications for which Synacthen proves effective and safe could it even be considered a possible potential new entrant, as Humana admits when excluding from its proposed market definition ‘short-acting ACTH drugs.’”).

a. Industry or public recognition of the submarket as a separate economic entity

Plaintiff alleges that “[l]ong-acting ACTH drugs are recognized by Mallinckrodt, medical providers, and the public as differentiated from other adrenal hormone drugs.” SAC ¶ 89.a.; see also id. ¶ 50 (“Acthar . . . appears to be viewed by certain providers or patients as distinct from corticosteroids.”). For example, “the widely-used First Data Bank (FDB) drug database” classifies corticosteroids like prednisone in a separate Therapeutic Class from Acthar and other ACTH drugs. Id. ¶ 52. Additionally, Defendant has acknowledged in its public filings that Acthar “has limited direct competition due to the unique nature of the product.” Id. ¶ 61.

On the other hand, Plaintiff alleges that Defendant has “aggressively marketed” “studies . . . that claim to show clinical evidence supporting the superiority of Acthar compared with corticosteroid drugs.” SAC ¶ 51. However, this seems to support, rather than refute, the idea that Acthar and corticosteroids are in the same market. See Hicks, 897 F.3d at 1122 (“claims of increased effectiveness” of products in the proposed submarket does not “place” those products “in a distinct market”). And Plaintiff also alleges that the FTC “recognized ‘ACTH drugs’ as a relevant antitrust market when evaluating [Defendant’s] acquisition of Synacthen.” SAC ¶ 89.a.ii. As the Court noted in the March Order, however, the fact that the FTC required Defendant to grant a license only for the treatment of two specific indications “highlights the flaws in a market definition untethered to drugs that are reasonably interchangeable for a given condition.” March Order at 9 n.3.

Plaintiff’s allegations as to this factor cut both ways.

b. Product’s peculiar characteristics and uses

Plaintiff contends ACTH drugs have a “biological mechanism of action [that] is distinct from other drugs in that they stimulate the adrenal gland to produce cortisol” while “Glucocorticoid drugs . . . do not work through the adrenal gland.” SAC ¶ 89.b.i.; see also id. ¶ 51

(“Acthar’s mechanism of action is slightly different from that of corticosteroids”). Similarly, the only other drug approved to treat infantile spasms, Sabril, “is not a steroid, but is instead in a class of anticonvulsant drugs” that “works by inhibiting the breakdown of a particular neural transmitter.” *Id.* ¶ 49 n.3. Defendant contends “the new allegations regarding the nature of corticotropin and its mechanism of action do not negate the fact that for some indications, noncorticotropin treatments remain available.” Mot. at 8. And as the Court previously held, biological differences alone do not render ACTH drugs a distinct market. March Order at 7 n.2. However, the product’s “peculiar characteristics,” is one of many factors the Court is instructed to consider in determining whether the complaint has alleged a plausible submarket.

Importantly, Plaintiff also alleges ACTH drugs have uses different from other drugs used to treat the same conditions. For example, “Acthar is supposed to be a last-line treatment alternative that may be tried after corticosteroids have failed in the hope that Acthar, through its slightly different mechanism of action, may be effective where similar drugs have not been.” SAC ¶ 51; *see also id.* ¶ 89.d.i. (Acthar is supposed to be prescribed only where “those drugs have either failed to treat their conditions or those drugs are contraindicated for that patient.”); *id.* ¶ 89.d.iii (“Humana limits approved use of Acthar (other than for infantile spasms) under its policies to patients who have ‘contraindications or intolerance to corticosteroids that are not expected to also occur with’ Acthar”). And for infantile spasms, “Sabril may be used in combination with long-acting ACTH drugs, or it may be suitable where long-acting ACTH drugs have been ineffective at controlling infantile spasms or were not well tolerated by the patient.” *Id.* ¶ 49 n.3.² Defendant does not

² Defendant contends that “the fact that ‘Sabril may be used in combination with long-acting ACTH drugs’ (SAC ¶ 49 n.3) creates no fact issue as to whether it is not an alternative but a complementary product, like software is to hardware.” Dkt. 78 (Reply) at 2 n.1 (citing Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* § 565a (4th ed. 2020)). Defendant does not

address these allegations, focusing solely on the fact that long-acting ACTH drugs are FDA approved to treat the same conditions as other drugs.³ But, Plaintiff has adequately alleged that, although ACTH drugs and other drugs can be used to treat the same conditions, they are not interchangeable in that doctors or patients are not choosing between long-acting ACTH drugs and other drugs at any given time. Rather, doctors and patients are only turning to long-acting ACTH drugs when other drugs are not an option. This supports a long-acting ACTH submarket.

c. Unique production facilities

Plaintiff alleges that “Acthar is produced at only one facility in Prince Edward Island, Canada . . . using a complex, biologic process that is difficult to replicate” while “Glucocorticoid drugs are synthesized by manufacturers of chemicals for pharmaceuticals in a variety of facilities throughout the world” that “are not equipped to produce Acthar, nor could they be easily modified in order to do so.” *Id.* ¶ 89.c. This supports a long-acting ACTH submarket.

d. Distinct customers

As discussed above, Plaintiff alleges that “[u]sers of Acthar are distinct from users of other adrenal hormone drugs because” Acthar is only supposed to be prescribed where “those drugs have either failed to treat their conditions or those drugs are contraindicated for that patient.” *Id.* ¶ 89.d.i.; *see also id.* ¶ 89.d.iii (“Humana limits approved use of Acthar (other than for infantile spasms) under its policies to patients who have ‘contraindications or intolerance to corticosteroids that are not expected to also occur with’ Acthar”). Plaintiff further

explain why this is so. Further, at this stage, Plaintiff need not create a fact issue. All factual allegations are accepted as true.

³ That Defendant glossed over the import of these new allegations is evident by Defendant’s incorrect claim that Plaintiff “attempts to justify the[] exclusion [of other drugs] based *solely* on its allegation that ‘the drugs exhibit a very low degree of cross-price elasticity.’” Reply at 1.

alleges that “Acthar is inappropriately prescribed as a result of bribes paid to doctors . . . for patients for whom corticosteroids are an appropriate medical and economic substitute” and “[a]bsent the illegal bribe, Acthar would not be prescribed for these patients.” *Id.* ¶ 89.d.ii. Defendant contends this allegation “confuses the issue more” because Plaintiffs describe Acthar and corticosteroids as “appropriate medical and economic substitute[s].” Mot. at 7. However, the Court understands Plaintiff’s allegation to acknowledge that Acthar is considered for the same type of consumers (or the same uses) only where doctors are choosing to prescribe Acthar improperly and illegally. Because the parties do not address it, the Court assumes, without deciding, that where a Defendant’s alleged illegal conduct causes products to be treated as substitutes when they otherwise would not be, the products are not treated as substitutes for market definition purposes. Therefore, this supports a long-acting ACTH submarket.

e. Distinct prices and sensitivity to price changes

Plaintiff alleges that “Acthar’s price to Humana in 2019 averaged more than \$65,000 per prescription, more than 650,000% of the average prescription price for a glucocorticoid drug (\$9.79),” *id.* ¶ 89.e.i., and “[t]he price of Acthar has increased repeatedly and substantially while the price of other Glucocorticoid drugs has decreased,” *id.* ¶ 89.f.i.; see also id. ¶ 62 (from 2011 to 2019 the price of Acthar increased while the price of Glucocorticoid drugs decreased, but the quantity of Acthar reimbursed by Plaintiff substantially increased, while the quantity of reimbursed Glucocorticoid drugs decreased). If the two drugs were economic substitutes, the increasing price disparity between Acthar and Glucocorticoid drugs would have caused consumers to switch from Acthar to Glucocorticoid drugs, but that was not the case. This was confirmed through Plaintiff’s economic analysis of the cross-price elasticity of demand provided in the SAC. *Id.* ¶¶ 63-64.

Defendant challenges Plaintiff's analysis on a number of grounds.⁴ However, these criticisms appear better directed to a challenge at the summary judgment stage based on the parties' expert opinions. For example, Defendant contends the cross-elasticity number is unhelpful because it aggregates indications and excludes non-glucocorticoid alternatives "making it impossible from the allegations to discern whether a positive cross-elasticity of demand exists between ACTH and non-ACTH drugs when used to treat some conditions while a negative cross-elasticity of demand exists when used to treat others." Mot. at 9. Defendant contends the SAC itself "suggest[s] Acthar faces different levels of competition between indications – from glucocorticoids for some indications and from non-glucocorticoid alternatives for others." *Id.* However, beyond infantile spasms, for which glucocorticoids are not FDA approved, the SAC gives no reason to assume that cross-elasticity of demand would be positive for some indications and negative for others. And Plaintiff does not allege that non-glucocorticoid alternatives exist for indications other than infantile spasms. *See* Opp'n at 7 ("Humana believes that no such [non-glucocorticoid alternatives] exist, so it cannot be expected to have identified them itself").

As to infantile spasms, Plaintiff did not perform a cross-elasticity analysis with Sabril. Defendant contends Plaintiff's "argument that Sabril is irrelevant because the [infantile spasm] market is small, and not because of any low cross elasticity of demand (Opp. 8, n.11), is telling." Reply at 2 n.1. However, Defendant points to no requirement that at the motion to dismiss stage, a Plaintiff must perform a statistical econometric analysis of the cross-elasticity of every potential substitute. Plaintiff has alleged that Sabril's characteristics and uses are materially different; that is sufficient at this stage.

⁴ Defendant contends the March Order rejected the factual premise that Defendant was able to raise its price without losing sales. Reply at 1 (citing March Order at 11). But all the Court held was that none of the allegations in the FAC supported that claim. Plaintiff has now added such allegations.

Defendant also contends that because the analysis begins in 2011, it does not exclude any “continuing loss of sales to corticosteroids resulting from the 2007 price adjustment for Acthar and related formulary restrictions” and it also “ignor[es] myriad factors affecting supply and demand for conditions for which Acthar is not commonly used.” Reply at 2. Plaintiff need not exclude all potentially relevant or confounding factors in the rough cross-elasticity analysis set forth in its complaint. Plaintiff’s proposed submarket need only be plausible; it need not be proven.

Finally, Defendant contends Plaintiff’s analysis is flawed because it relies only on its own data. Mot. at 9 n.3. However, Plaintiff covers millions of patients and therefore – particularly at the motion to dismiss stage – its own data can serve as a proxy for the “aggregate demand of consumers.” Id.

Therefore, this factor supports a long-acting ACTH submarket.

f. Specialized vendors

Plaintiff alleges “Acthar is distributed only through a limited network of specialty pharmacies . . . , while other adrenal hormone drugs are widely available through tens of thousands of retail and other mainstream pharmacies throughout the country (e.g. CVS, Rite Aid, Walgreens)” because “Acthar requires special handling that retail pharmacies are not well equipped to provide.” SAC ¶ 83.g.i. This supports a long-acting ACTH submarket

Based on the Brown Shoe factors, the Court concludes Plaintiff has adequately pled a submarket for long-acting ACTH drugs.⁵

2. Antitrust Injury

Plaintiff alleges it was harmed by Defendant’s unlawful conduct because it otherwise “would have paid for fewer Acthar prescriptions and it would have paid less for those prescriptions” because “increased

⁵ The Court therefore need not, and does not, address Plaintiff’s additional allegations in support of direct proof of market power.

competition [from Synacthen] in the market for long-acting ACTH drugs” would have resulted in “lower prices for Acthar” or more prescriptions for the “lower priced Synacthen.” SAC ¶ 137. Defendant contends this presumption depends on a speculative chain of events that if Defendant had not purchased the Synacthen rights, another company “would have secured FDA approval . . . , entered the relevant antitrust market, and gained acceptance among doctors, thereby causing a reduction in the prices that [Plaintiff] paid for Acthar.” Mot. at 10.

Plaintiff argues the allegations in the SAC “are beyond sufficient to make it *plausible* that Synacthen would have been sold in the United States but for Mallinckrodt’s conduct.” Opp’n at 9-10. Specifically, Plaintiff has alleged that Synacthen has been used safely and effectively outside the United States and therefore “a buyer would not need to begin the research, development, testing, or manufacturing process from scratch,” SAC ¶ 70, 75, that Defendant used Synacthen studies to obtain FDA approval for Acthar, *id.* ¶ 71, that the FDA has approved a short-acting formulation of Synacthen, *id.* ¶ 75 n.7, and that there were three other bidders seeking the rights to pursue FDA approval for Synacthen and commercialize it in the United States that had the necessary expertise and financing, as well as sufficient business and regulatory plans, to do so, *id.* ¶¶ 73-74. The Court agrees this is more than sufficient. *See Bubar v. Ampco Foods, Inc.*, 752 F.2d 445, 452 (9th Cir. 1985) (courts consider “[t]he background and experience of [the potential entrant] in his prospective business,” “[a]ffirmative action on the part of [a potential entrant] to engage in the proposed business,” “ability of [a potential entrant] to finance the business and the purchase of equipment and facilities necessary to engage in the business,” and “consummation of contracts” by a potential entrant).

Defendant raises a number of reasons why it believes these allegations are insufficient, none of which the Court finds persuasive. First, Defendant contends that “[c]ourts addressing this issue have required a plaintiff to plead facts establishing the probability and timing of FDA approval for an unapproved drug to be considered a

potential competitor.” Mot. at 12 (citing Andrx Pharm., Inc. v. Biovail Corp. Int’l, 256 F.3d 799, 807-08, 815 (D.C. Cir. 2001) and Brotech Corp. v. White Eagle Int’l Techs. Grp., Inc., No. CIV.A.03-232, 2004 WL 1427136, at *6 (E.D. Pa. June 21, 2004)). This presumably stems from the requirement that to establish causation in a competitor exclusion case, the plaintiff must allege that the potential competitor has an “intent to enter the market and a preparedness to do so.” See Bubar, 752 F.2d at 450.⁶ Under Defendant’s view, the probability and timing of FDA approval are necessary to make plausible allegations that a competitor is prepared to enter the market. However, particularly where the plaintiff is a consumer rather than a competitor, and where, as here, the defendant is currently in possession of the “asset package,” it would be too exacting a burden to require a plaintiff to allege exactly how long it would take for some other company to get FDA approval. Plaintiff’s allegations make it sufficiently plausible that, but for Defendant’s purchase of the Synacthen rights, Synacthen would have been approved by the FDA for use in the United States for at least one of the same indications as Acthar. That in Brotech the plaintiff had failed to allege when FDA approval “may be anticipated,” 2004 WL 1427136, at *6, and in Tawfilis v. Allergan, Inc., 157 F. Supp. 3d 853

⁶ Plaintiff asserts the cases cited by Defendant address antitrust cases brought by competitors and not consumers, for which there are different burdens. Opp’n at 10-11. However, the circuit courts to have considered the issue have concluded that both consumers and competitors must satisfy the intent and preparedness test. See, e.g., Meijer, Inc. v. Biovail Corp., 533 F.3d 857, 862 (D.C. Cir. 2008) (“Just as a would-be entrant suing an incumbent firm for excluding it from a relevant market in violation of the Sherman Act must demonstrate it intended and was prepared to enter that market, . . . so a would-be purchaser suing an incumbent monopolist for excluding a potential competitor from which it might have bought a product at a lower price must prove the excluded firm was willing and able to supply it but for the incumbent firm’s exclusionary conduct” (internal citations omitted)); Sunbeam Television Corp. v. Nielsen Media Research, Inc., 711 F.3d 1264, 1273 (11th Cir. 2013) (following Meijer and rejecting position that “proof of a ‘willing and able’ competitor ‘standing in the wings, ready to swoop in’ should only apply to *competitor* plaintiffs, not *customer* plaintiffs.”).

(C.D. Cal. 2015), the plaintiff had alleged that approval “could have” occurred within two years, id. at 857, does not impose a requirement on all plaintiffs to allege the number of years in which approval is likely to occur. In each of those cases, the court considered the totality of the allegations and concluded that antitrust injury either was or was not plausible. Most of the other cases cited by Defendant were decided at the summary judgment stage and are therefore inapplicable here.

Next, Defendant contends that although it has been three years since it was required to sublicense the rights to Synacthen for infantile spasms and nephrotic syndrome to another company, id. ¶ 82, the complaint contains no allegations that Synacthen has obtained FDA approval, or even that the sublicensee has made progress in obtaining FDA approval. Mot. at 13. According to Defendant, this makes it implausible that Synacthen would have been approved by the FDA if another bidder had purchased it in 2013. However, a potential entrant that has the rights to develop and sell Synacthen for only two indications is not similarly situated to a potential entrant that can develop and sell Synacthen for any indication. This is particularly true here where Plaintiff has alleged that the indications for which Defendant retained rights are the cash cows. See, e.g., SAC ¶ 114 (“[F]ewer than 10% of Acthar’s sales come from prescriptions for infantile spasms, and more than 98% of Humana’s expenditures for Acthar were made for insureds over the age of 18”). Therefore, this does not make Plaintiff’s allegations implausible.

Defendant also contends that because Synacthen is a synthetic drug, it “cannot be presumed to have identical effects on the human body” and therefore would be approved by the FDA for the same 19 indications. Mot. at 11; see also id. at 13 (“Humana makes no specific allegations regarding Synacthen’s use and effectiveness as to any particular Acthar indication, let alone its relative safety and effectiveness versus Acthar as to such indications”). However, that Defendant used Synacthen studies when it applied for FDA approval and that Synacthen is used for the same indications outside of the United States makes it plausible that Synacthen would be approved for those indications in the United States. Therefore, the Court need not

simply “guess as to whether . . . Synacthen is a plausible replacement for Acthar as the standard of care for [infantile spasms] in the United States, and whether, for other indications, it would be one of several alternatives for ‘first line’ treatment or an alternative to Acthar as a ‘last line’ treatment.” Reply at 5. Moreover, the Court agrees with Plaintiff that it “has suffered antitrust injury if it is plausible that a finder of fact could conclude that Synacthen would have been approved for any use, as the introduction of competition would lower the price of all ACTH drugs.” Opp’n at 10 n.12. There are no allegations that the price of Acthar differs depending on the indication. Therefore, competition for less than all 19 indications could plausibly lower the price for all indications.

Finally, Defendant argues that Plaintiff has not plausibly alleged that the beginning of the alleged antitrust period should be 2011. See Mot. at 13. The bidding process for the rights to sell Synacthen in the United States did not begin until late 2012 and early 2013, and Defendant did not win the rights until June 11, 2013. SAC ¶¶ 76-77. Plaintiff fails to explain how any harm caused by Defendant’s alleged anticompetitive behavior could have occurred prior to Defendant acquiring the Synacthen license. However, the date another bidder could have or would have brought Synacthen to market is a factual question not best resolved at the motion to dismiss stage. Moreover, discovery might reveal that, had it not won the bid, Defendant would have started lowering its prices prior to Synacthen’s market entrance in anticipation of future competition.

The Court concludes Plaintiff has adequately alleged an antitrust injury.

3. Statute of Limitations

Defendant contends that 22 of the 25 state laws relevant to Plaintiff’s state antitrust claims are barred by the statute of limitations because “[a] cause of action for an allegedly anticompetitive acquisition of assets accrues on the date of the acquisition,” which in this case was June 11, 2013, and that statute of limitations for those 22 states is four

years or less. Mot. at 14.⁷ Plaintiff contends its claims were tolled due to fraudulent concealment, the continuing violation doctrine, and American Pipe tolling. Opp’n at 14-19.

a. Fraudulent Concealment

Plaintiff alleges it “could not have discovered and remained unaware” of Defendant’s illegal conduct until the FTC brought these actions to light in 2017 because Defendant “falsely maintained that it would develop and seek FDA approval of Synacthen.” SAC ¶¶ 131-132. For example, Defendant’s chief scientific officer made public statements that Defendant intended to seek FDA approval for Synacthen in conditions different than Acthar and where Synacthen would “potentially provide a clinical benefit over Acthar.” Dkt. 70-2 (RJN Ex. B) (June 2013 Press Release).⁸ However, Plaintiff’s Section 2 claim explicitly alleges that Defendant’s purchase of the license itself, not its failure to commercialize the drug, is the anticompetitive behavior. See SAC ¶ 141 (Section 2 claim alleges that “[b]y intervening in the bidding process for Synacthen and purchasing the exclusive license to market Synacthen in the United States, Mallinckrodt eliminated the potential competitive threat posed by an independently owned Synacthen license”). In other words, as alleged, the “potential competitive threat” was an “independently owned Synacthen license.” Plaintiff should have been aware that there would be no independently owned

⁷ Plaintiff agrees that these 22 states have limitations periods of four or fewer years for antitrust claims, but contends that for two of those states, New York and Oregon, the antitrust claim was statutorily tolled “for one year after the conclusion of any proceeding instituted by the United States under federal antitrust laws.” Opp’n at 19. Defendant appears to concede that these are not time-barred. See Reply at 6 n.3. Therefore, the parties agree that 20 of 25 states relevant to Plaintiff’s state antitrust claim are subject to a statute of limitations defense.

⁸ The Court grants Plaintiff’s unopposed request for judicial notice (Dkt. 70) of a press release issued by Defendant in June 2013. Fed. R. Evid. 201(b).

Synacthen license at the time Defendant publicly announced it would be obtaining the license.

Plaintiff's other allegations provide further support for this conclusion. For example, Plaintiff alleged that "given the drugs' similarities, any therapeutic indication that [Defendant] might have pursued with Synacthen could have been pursued with Acthar." Id. ¶ 79. Plaintiff also alleged that "Novartis was not naïve, and could be expected to understand that Questcor would have little interest in developing the only synthetic competitor to Acthar, its extraordina[r]ily lucrative non-synthetic product." Id. ¶ 78. Plaintiff does not explain why it could not have been expected to understand the same thing. Accepting as true the allegation that Defendant falsely stated that it would obtain FDA approval of Synacthen for certain treatments, there are no allegations in the complaint that would support the necessary assumption that had Defendant developed, obtained FDA approval for, and sold Synacthen in the United States, Plaintiff could have reasonably expected to have either paid lower prices for Acthar or that Synacthen would have been offered by Defendant at a materially lower price. Given that Defendant would still control 100% of the alleged product market, whether through one drug or two, the Court cannot plausibly draw the inference that Plaintiff was reasonable in assuming Defendant would have acted to its financial detriment and lowered the price of Acthar or introduced Synacthen at a substantially lower price. See Iqbal, 556 U.S. at 679 (Courts must "draw on their judicial experience and common sense" in determining whether allegations in a complaint are plausible). Fraudulent concealment, therefore, does not save Plaintiff's otherwise time-barred claims.⁹

⁹ Plaintiff's footnote implicitly arguing that the Court should find fraudulent concealment here because of the Court's conclusion as to Plaintiff's RICO claim, Opp'n at 15 n.20 (citing March Order at 25), is misplaced. The facts necessary to put Plaintiff on inquiry notice of the RICO claims differs materially from the types of facts that would put Plaintiff on inquiry notice of the antitrust claims.

b. Continuing Violation

Plaintiff also contends that Defendant's actions constitute a continuing violation because "its yearly licensing payments to Novartis have forestalled and continue to forestall the transfer of Synacthen rights to a party that would develop it to compete with Acthar." Mot. at 18.¹⁰ Specifically, Defendant pays Novartis \$25 million each year to maintain its monopoly in the long-acting ACTH market and Plaintiff contends that "[e]ach payment is anticompetitive in that it forestalls Novartis from licensing its drug to others and enables Mallinckrodt to charge monopoly prices." Id. Essentially, each payment is a new contract preventing Synacthen from being developed to compete with Acthar. The Court agrees.

"To state a continuing violation of the antitrust laws in the Ninth Circuit, a plaintiff must allege that a defendant completed an overt act during the limitations period that meets two criteria: '1) It must be a new and independent act that is not merely a reaffirmation of a previous act; and 2) it must inflict new and accumulating injury on the plaintiff.'" Samsung Elecs. Co. v. Panasonic Corp., 747 F.3d 1199, 1202 (9th Cir. 2014) (quoting Pace Indus., Inc. v. Three Phoenix Co., 813 F.2d 234, 238 (9th Cir. 1987)). Cases where "all of the harm occurred at the time of the initial violation . . . is the exception, not the rule. Id. at 1202-03. Instead, "[n]on-legal actions taken pursuant to a pre-limitations period contract can lead a new cause of action to accrue." Id. at 1203.

Defendant first contends the continuing violation theory does not apply because "[u]nilateral decisions about whether to develop a new product . . . are *not* subject to antitrust scrutiny." Reply at 6. However, Plaintiff is not claiming anticompetitive conduct simply because Defendant chose not to develop an Acthar competitor. The anticompetitive conduct stems from Defendant's decision to prevent

¹⁰ The Court grants Plaintiff's unopposed request for judicial notice (Dkt. 70) of Defendant's SEC filings and the license agreement with Novartis (Dkts. 70-1, 70-3 through 70-8). Fed. R. Evid. 201(b).

others from developing an Acthar competitor by continuing to pay Novartis for the Synacthen license. Therefore, the Court finds this argument unconvincing.

Next, Defendant contends the continuing violation theory does not apply because “the license agreement [does not] contain[] a provision requiring [Defendant] to ‘shelve’ Synacthen.” Reply at 7. However, Defendant cites no case law imposing a requirement for the agreement to explicitly compel the anticompetitive conduct. Moreover, the license agreement itself explicitly prevents companies other than Defendant from developing Synacthen for sale in the United States, thereby proscribing any independently owned Synacthen license, the anticompetitive conduct at issue here. And “action taken under a pre-limitations contract [i]s sufficient to restart the statute of limitations so long as the defendant had the ability not to take the challenged action, even if that would have required breaching the allegedly anti-competitive contract.” Samsung, 747 F.3d at 1203.

Finally, Defendant contends recent cases have held that the continuing violation theory does not apply to antitrust allegations based on price increases after an acquisition. Reply at 7-8 (citing Midwestern Mach., Inc. v. Nw. Airlines, Inc., 167 F.3d 439, 440 (8th Cir. 1999) and Z Techs. Corp. v. Lubrizol Corp., 753 F.3d 594, 603 (6th Cir. 2014)). These cases are factually distinct from the alleged antitrust violations at issue here, which involve more than an incidental price increase ultimately caused by an acquisition. Here, the antitrust conduct is the continuing payments to Novartis to prevent another company from developing an Acthar competitor. A similar arrangement was found to be a continuing violation by the Ninth Circuit in Samsung. 747 F.3d at 1204 (because “the license itself did not permanently and finally control the acts of the SD Defendants[,] [t]heir decision to enforce the contract caused a new anti-competitive harm, and the statute of limitations ran anew from the time that defendants began enforcement.”). To the extent the cases cited by Defendant contradict Ninth Circuit law as set forth in Samsung, the Court disregards them.

Therefore, the statute of limitations does not bar Plaintiff from asserting claims based on harms flowing from the alleged anticompetitive license payments made to Novartis during the limitations period.

c. American Pipe Tolling

Plaintiff contends it is also “entitled to tolling of its claims under *American Pipe* as of [April and October of 2017 when class actions were filed against Defendant], because in those cases [Plaintiff] is a putative member of the classes and its antitrust claims share a common factual and legal basis with the claims asserted.” Opp’n at 15 n.21. Defendant notes that only the April 2017 lawsuit would fall within the statute of limitations, but Plaintiff was not included in the proposed class until an amended complaint was filed in December 2017, after the expiration of the four-year limitations period. See Reply at 8. Therefore, American Pipe does not save Plaintiff’s state law claims to the extent based on the 2013 license agreement.¹¹

Defendant’s motion to dismiss the First and Second Counts is DENIED. Defendant’s motion to dismiss the Third Count is DENIED as to claims brought under New York, Oregon, Maine, Vermont, and Wisconsin law. As to the remaining state law antitrust claims, Defendant’s motion is GRANTED to the extent Plaintiff seeks to challenge the 2013 license agreement (and any other conduct outside of the relevant limitations period), but DENIED as to Defendant’s alleged continuing antitrust violations within the limitations period.

¹¹ It does not appear that Defendant disputes that the complaints filed on October 30, 2017 and December 8, 2017 would toll the statute of limitations for claims based on conduct that occurred within four years of those dates.

B. RICO (Counts IV and V)

The Court previously held that Plaintiff had adequately alleged RICO claims based on an alleged “Acthar Enterprise,” consisting of Defendant, CDF, and the prescribing doctors, that participated in a pattern of racketeering activity including 1) mail and wire fraud based on Defendant’s and prescribing doctors’ misrepresentations that they were complying with state and federal law, when in fact a) the co-pay assistance programs violated the Anti-Kickback Statute (AKS) and the False Claims Act (FCA), and b) the doctor payments violated state bribery laws and 2) bribery based on the doctor payments. March Order 13-34.¹² In so deciding, the Court rejected Defendant’s contention that any racketeering acts related to the co-pay assistance funds occurred outside the four-year statute of limitations. Id. at 23-25.

Defendant now contends that the Court’s “reasoning [on the statute of limitations issue] invites consideration of judicially noticeable facts establishing that the claim is time-barred.” Mot. at 3.¹³ Defendant identifies a 2013 New York Times article that purportedly establishes that Humana “would have been on notice of its alleged claim” more than four-years before it filed this action. Id. at 4; see also id. at 18 (“the alleged conduct has been public knowledge since 2013”), id. at 19 (“major news media reported – as early as 2013 – about Questcor’s alleged contributions to the CDF funds at issue and their purported Acthar-only nature”). However, Defendant does not explain

¹² The Court also held that Plaintiff had not adequately alleged any racketeering activity based on alleged insured misrepresentations or the theory that co-pay assistance was bribery. March Order at 26-28. The Court invited Plaintiff to amend those claims to the extent it wished to continue pursuing them. Id. at 35 n.21. Because Plaintiff chose not to amend those claims, it has abandoned them. For the sake of clarity, the Fourth and Fifth Counts, to the extent they rely on either of these theories, are DISMISSED.

¹³ Defendant concedes it is not entitled to dismissal based on the allegations in the SAC alone. See Mot. at 19 (Defendant “agrees that [Plaintiff] had not pled admissions on the critical issue of what it knew about the CDF funds at the time”).

how the Court's reasoning in the March Order warrants reconsideration of the statute of limitations issue. The Central District of California permits only three grounds on which a motion for reconsideration may be made:

- (a) a material difference in fact or law from that presented to the Court before such decision that in the exercise of reasonable diligence could not have been known to the party moving for reconsideration at the time of such decision, or
- (b) the emergence of new material facts or a change of law occurring after the time of such decision, or
- (c) a manifest showing of a failure to consider material facts presented to the Court before such decision.

Local Rule 7-18. The new article is at best a material difference in fact, but Defendant makes no argument that it could not have discovered the article in the exercise of reasonable diligence prior to the March Order. Therefore, the Court declines to reconsider its prior determination that Plaintiff had adequately alleged it discovered Defendant's wrongdoing within the limitations period.

Further, as Plaintiff points out, even if the Court were to consider the article, it would not change the outcome. One or two articles are insufficient to show, as a matter of law, that Plaintiff had constructive notice of the facts contained within them.¹⁴ Additionally, the Court previously concluded that because Plaintiff alleged that the donation agreements fraudulently misrepresented that the funds were not limited to patients using Acthar, had Plaintiff inquired into the funds,

¹⁴ Defendant contends that its argument is not that the articles themselves should have put Plaintiff on notice, but that the OIG's 2014 SAB, which purportedly singled out the emergence of single-drug funds, should have caused Plaintiff to run some Google searches to see if there were any articles about drugs covered by Plaintiff. Reply at 11. Whether Plaintiff's investigation (or lack thereof) in response to the 2014 SAB was reasonable is a factual issue not best resolved at the motion to dismiss stage.

it would not have discovered that the funds were illegal. March Order at 24-25.

Defendant's motion to dismiss Counts Four and Five to the extent based on allegations regarding co-pay assistance programs is DENIED.

C. State Law Claims (Counts VI through X)

1. Statute of Limitations

Defendant contends that 21 of the 25 states' laws under which Plaintiff brings its unfair competition and consumer fraud and deceptive trade practices claims, as well as four of the five states' laws under which Plaintiff brought an insurance fraud claim are also barred by the relevant statutes of limitations to the extent they are based on the co-pay assistance funds. Mot. at 20. The Court declines to dismiss those claims for the same reason stated in section III.B. and for the additional reason that Defendant did not raise this contention in its prior motion and therefore is prohibited from doing so here under Rule 12(g)(2). See In re Apple iPhone Antitrust Litig., 846 F.3d 313, 317-318 (9th Cir. 2017), aff'd sub nom. Apple Inc. v. Pepper, 139 S. Ct. 1514 (2019) ("a defendant who fails to assert a failure-to-state-a-claim defense in a pre-answer Rule 12 motion cannot assert that defense in a later pre-answer motion under Rule 12(b)(6)").

2. Individual Defenses to State Laws

Defendant next contends Plaintiff's claims under Kentucky and New Jersey insurance fraud statutes also fail because the Kentucky statute requires a criminal adjudication of guilt and the New Jersey statute requires "prelitigation notice . . . with which [Plaintiff] has not alleged compliance." Mot. at 15 n.8. Not only does Rule 12(g)(2) prevent Defendant from making these arguments in a successive pre-answer motion to dismiss, but it is also legally incorrect. As Plaintiff notes, the Kentucky legislature repealed the requirement of criminal adjudication. See 2018 Kentucky Laws Ch. 178 (HB 323) (removing requirement of a "criminal adjudication of guilt" for a private party to

state a claim for damages). And as to the New Jersey statute, prelitigation notice is not required. See N.J. Stat. § 17:33A-7(c) (notice to be provided at the time of filing). In reply, Defendant appears to concede that Plaintiff can assert its claim under New Jersey law. Reply at 12 (“Mallinckrodt requests that the Court dismiss with prejudice . . . all other claims (except that under New Jersey’s Insurance Fraud Statute)”).

Defendant attaches to its brief “Appendix B,” a chart of legal defenses to Plaintiff’s unfair competition and consumer fraud and deceptive trade practices claims. See Mot. at 23-25. That chart includes the following arguments:

- Michigan’s statutes do not apply to regulated activities, such as the provision of prescription drugs to Medicare beneficiaries, or alleged misrepresentations not made to customers
- Minnesota’s statutes require claims to satisfy the public benefit requirement and therefore do not apply to claims for recovery of private damages
- New Jersey’s statutes do not permit claims brought by third-party payors, rather than drug consumers
- North Dakota’s statutes do not apply to statements made in connection with coverage, rather than in connection with the sale or advertisement of a drug

Although technically within the 25-page limit, Appendix B skirts the purpose of the page limitation by including additional argument in size 11 font, single-spaced. Moreover, the arguments were not raised in the prior motion and are therefore improper under Rule 12(g)(2). The Court will not consider these additional defenses at this time.

3. Tortious Interference

The Court previously dismissed Plaintiff’s tortious interference claim because Plaintiff had failed to allege that accepting co-pay

assistance caused its members to breach their contract with Plaintiff. March Order at 34. Plaintiff has added allegations that its contracts with its members “provide[] that an insured is ‘responsible for’ copayments and ‘must pay [their] share of the cost when [they] get [a] service or drug.’” SAC ¶ 202. The contract also states that “when you get a drug through a patient assistance program offered by a drug manufacturer . . . we will not pay for any share of these drug costs.” Id. Plaintiff contends that “[i]f the [patient assistance program] uses its funds to pay the member’s co-pay, however, then both the letter and the purpose of the [contract] provision are subverted.” Id. ¶ 203.

But nothing in the cited provisions can reasonably be read as preventing members from paying their co-pays with money obtained from a co-pay assistance fund. The first provision, as discussed in the March Order, merely requires members to pay their co-pays. It sets no limitations on the source of the funds. The second provision, when read in context, does not prohibit members from doing anything at all. It is only a reminder that if members obtain drugs outside of their plan benefits directly from the drug manufacturer through a patient assistance program, Plaintiff will not reimburse members for any payments made to the patient assistance programs. Here, in contrast, the members do obtain the drugs through their insurance, and simply obtain the funds to pay the co-pays through a co-pay assistance fund. That is not prohibited by the contracts. The contract does not say that if a co-pay assistance fund covers the co-pay, Plaintiff was entitled to deny coverage in the first place, when it otherwise would have provided coverage. Moreover, there is simply nothing in the cited provision that requires members to “identif[y]” whether co-pay assistance “originat[ed] with the manufacturer.” Id. Therefore, it does not follow that “it is a breach for the member to use that assistance to procure payment for the manufacturer’s drug.” Id.; see also id. (“Mallinckrodt is causing Humana members to procure a benefit under the contract to

which the members are not entitled under the contract's plain terms.")¹⁵

Therefore, Plaintiff has still not alleged that its members breached their contracts, and the Court determines that Plaintiff cannot plead any other facts that would cure this deficiency. See Schreiber, 806 F.2d at 1401 (leave to amend may be denied when "the court determines that the allegation of other facts consistent with the challenged pleading could not possibly cure the deficiency"). Count IX is DISMISSED with prejudice.

IV. CONCLUSION

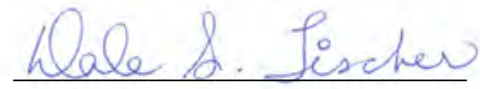
Count III, to the extent it relies on laws from states other than New York, Oregon, Maine, Vermont, and Wisconsin and relies on the 2013 license agreement, Counts IV and V, to the extent they rely on purported racketeering activity based on alleged insured

¹⁵ In half a sentence Plaintiff contends that members' acceptance of co-pay assistance is alternatively "disruption' of the contractual relationship." Opp'n at 21 (citing Redfearn v. Trader Joe's Co., 230 Cal. Rptr. 3d 98, 104 (2018)). This is insufficient to preserve this argument. See Birdsong v. Apple, Inc., 590 F.3d 955, 959 (9th Cir. 2009) ("[A] bare assertion does not preserve a claim, particularly when, as here, a host of other issues are presented for review."); see also Indep. Towers of Washington v. Washington, 350 F.3d 925, 929-30 (9th Cir. 2003) ("However much we may importune lawyers to be brief and to get to the point, we have never suggested that they skip the substance of their argument in order to do so. . . . We require contentions to be accompanied by reasons."); Mahaffey v. Ramos, 588 F.3d 1142, 1146 (7th Cir. 2009) ("Perfunctory, undeveloped arguments without discussion or citation to pertinent legal authority are waived").

misrepresentations or the theory that co-pay assistance was bribery, and Count IX are DISMISSED with prejudice. Defendant's motion is otherwise DENIED.

IT IS SO ORDERED.

Date: August 14, 2020

A handwritten signature in blue ink that reads "Dale S. Fischer". The signature is written in a cursive style and is positioned above a horizontal line.

Dale S. Fischer
United States District Judge

From: CHRISTOPHER.HARRIS@lw.com
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Subject: [EXT] RE: Omnibus unsubstantiated claims objection

That is fine thanks.

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Subject: RE: Omnibus unsubstantiated claims objection

Chris,

We have no objection to your proposal, provided that our admin and estimation motions stay on calendar for June 7.

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Subject: Omnibus unsubstantiated claims objection

*** EXTERNAL EMAIL ***

Counsel, we believe that the parties would benefit from clarity from the Court as to the scope of relevant discovery (both documents and deposition topics). The Haviland Hughes Plaintiffs have filed a motion to compel on document discovery to be heard on June 2, and we think it would make sense to get the Court's guidance then on the related scope of depositions as well. We think therefore it makes sense to move the 30b6 deposition until the week of June 1 after we get the Court's guidance. We have also heard from the Insurance Claimants that they need more time to review the Committee document production. To allow time for any additional production and review, we will adjourn the hearing on the unsubstantiated claims objection for two weeks to the week of June 21.

In addition, we also understand you wish to file a supplemental objection or other briefing after the 30b6 deposition, in which case we will file our reply brief five business after your supplemental briefing.

If you object to this adjournment please let us know tomorrow; otherwise we will reach out to the Court to find available dates for the week of June 21.

My apologies if I missed anyone who should be on this email.

Thank you.

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Subject: [EXT] RE: status conference; unsubstantiated claims hearing date

Hugh:

Agreed on both points below. However, I think we need to address your reply date. Would July 9 work? That would give you three weeks from the date we filed our brief, and also give us ample time with your papers to prepare for the hearing.

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Subject: status conference; unsubstantiated claims hearing date

*** EXTERNAL EMAIL ***

Ben, All,

Two things:

First: We had agreed to have a status conference on your estimation motion at the conclusion of the 6/25 hearing. Assume we should just adjourn that to come at the conclusion of the unsubstantiated claims hearing. Let me know if you have any concerns.

Second: We learned belatedly that Stephen Welch cannot be available on July 13. The court's availability through mid-July is extremely limited. It looks like we can get July 23 instead. Does this work for your side? Sorry for this after all the back and forth to find a date—had a miscommunication on our end.

Best,
Hugh

Hugh Murtagh

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Subject: RE: Friday's hearing

That works.

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Subject: RE: Friday's hearing

*** EXTERNAL EMAIL ***

Ben,

As discussed, the court can give us July 13 starting at 1pm ET. We will file our reply brief by July 7. Haviland Hughes confirms it consents as well. We can take care of adjusting the schedule. Let me know of any issues, otherwise we'll get this done.

Thanks,
Hugh

Hugh Murtagh

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Sent: Monday, June 21, 2021 2:41 PM

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Cc: Simon, Keith (NY) <Keith.Simon@lw.com>; Harris, Christopher (NY) <CHRISTOPHER.HARRIS@lw.com>; Marks, Betsy (BN) <Betsy.Marks@lw.com>; Mispagel, Jeffrey (NY) <Jeffrey.Mispagel@lw.com>; Simon, Keith (NY) <Keith.Simon@lw.com>; Kirschner, Justin (NY) <Justin.Kirschner@lw.com>; Zottnick, Kelsey (CH) <Kelsey.Zottnick@lw.com>; Hong, Larry (NY) <Larry.Hong@lw.com>; Zablocki, Alexandra (NY) <Alexandra.Zablocki@lw.com>; Taousse, Nacif (NY) <Nacif.Taousse@lw.com>; Stearn@RLF.com; Merchant@RLF.com

Subject: RE: Friday's hearing

Hugh,

The end of next week likely would not work for me, as I have to fly to Phoenix next week for a hearing in another matter. Otherwise, this is fine with us. For the reply brief, assuming we are looking at something after July 4th, can we do 5 business days?

Benjamin P. McCallen

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From: Hugh.Murtagh@lw.com <Hugh.Murtagh@lw.com>

Sent: Monday, June 21, 2021 2:09 PM

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Cc: Keith.Simon@lw.com; CHRISTOPHER.HARRIS@lw.com; Betsy.Marks@lw.com; Jeffrey.Mispagel@lw.com; Keith.Simon@lw.com; Justin.Kirschner@lw.com; Kelsey.Zottnick@lw.com; Larry.Hong@lw.com; Alexandra.Zablocki@lw.com; Nacif.Taousse@lw.com; Stearn@RLF.com; Merchant@RLF.com

Subject: RE: Friday's hearing

*** EXTERNAL EMAIL ***

Ben, thanks—and adding the full crews for visibility.

We think this make sense. We would propose to contact chambers for the next available time starting with latter half of next week. If we get a date late next week, we would file the reply 3 days ahead of the hearing; if it gets pushed past that, we would file reply 5 days ahead of the hearing. (Judge Dorsey may be out the full week after July 4.) If this works for you we will confirm Haviland Hughes has no objection, and then reach out to chambers for a date. If the first date is well beyond mid-July, we will get back in touch with you before agreeing to anything.

Hugh Murtagh

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From: McCallen, Benjamin <BMcCallen@willkie.com>

Sent: Monday, June 21, 2021 12:04 PM

To: Murtagh, Hugh (NY) <Hugh.Murtagh@lw.com>

Subject: Friday's hearing

Hugh,

Following up on our conversation from Friday, I wanted to make a proposal relating to Friday's hearing. Happy to discuss via phone with you or the larger team if helpful.

We would agree to adjourn the Unsubstantiated Claims Objection hearing, which means you don't have to file your reply tomorrow, Welch does not have to take the stand and the Debtors can focus their time and attention this week on other matters. We can contact chambers and get a new hearing date for some time in mid-July, and re-set your reply date (we will want it well before 3 days in advance of the hearing, but we can figure that out once we have a hearing date).

All we ask in exchange is that the Debtors agree to withdraw their objection to producing documents relating to our pre-petition, non-admin claims on the basis of the Unsubstantiated Claims Objection. As a practical matter, what that means is that, consistent with the schedule ordered by the judge last week, we will serve you any remaining discovery requests by Wednesday, the Debtors will respond to those RFPs by July 2 (as they will for all other parties), and then engage with us in good faith on the scope of our requests, and produce documents consistent with the Court order. In the meantime, hopefully we make progress in mediation. If not, then all other rights reserved -- we can have the claims objection heard in a few weeks and if the Court grants it, you reserve the right to make any arguments you want about limiting other discovery, estimation, etc., in light of that ruling.

Benjamin P. McCallen

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Subject: [EXT] Unsubstantiated Claims Objection -- July 23

All,

Circling back to confirm that all parties have agreed July 23 works for the unsubstantiated claims objection hearing. As discussed earlier, we will file our reply brief no later than July 9. Please let us know of any issues.

Best,
Hugh

Hugh Murtagh

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**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:)	
)	Chapter 11
MALLINCKRODT., <i>et al.</i> ,)	
)	Case No. 20-12522 (JTD)
Debtors. ¹)	
)	(Jointly Administered)
)	
)	Re: D.I. 2165

**JOINT DEBTORS AND ATTESTOR/HUMANA
EXHIBIT & WITNESS LIST FOR JULY 23, 2021 HEARING**

Exhibit No.	Document Description
1.	List of 62 Non-Defendant Debtors showing how they are defined in the <i>Debtors' Omnibus Reply in Support of First Omnibus Objection to Unsubstantiated Claims (Substantive)</i> [Docket. No. 3177] (the " <i>Reply</i> ") (appended to Reply as <u>Exhibit A</u>)
2.	Transcript of Video Hearing Before the Honorable John T. Dorsey, United States Bankruptcy Judge, conducted Jun. 2, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) (appended to Reply as <u>Exhibit B</u>)
3.	Transcript of Video Hearing Before the Honorable John T. Dorsey, United States Bankruptcy Judge, conducted Jun. 29, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) (appended to Reply as <u>Exhibit C</u>)
4.	<i>Declaration of Stephen A. Welch, Chief Transformation Officer, in Support of Chapter 11 Petitions and First Day Motions</i> , dated Oct. 12, 2020, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 128]
5.	<i>Amended Verified Statement Pursuant to Rule 2019 of the Federal Rules of Bankruptcy Procedure of Acthar Plaintiffs' Counsel</i> , dated Feb. 24, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 1508]
6.	<i>Debtors' Omnibus Objection to Class Proofs of Claim</i> , dated Apr. 30, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 2164]
7.	<i>Order Granting the Debtors' Motion for Injunctive Relief Pursuant to 11 U.S.C. § 105</i> , dated Nov. 25, 2020, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD), Adv. Pro. No. 20-50850 (JTD) [Adv. Docket No. 170]

¹ A complete list of each of the Debtors in these chapter 11 cases may be obtained on the website of the Debtors' proposed claims and noticing agent at <http://restructuring.primeclerk.com/Mallinckrodt>. The Debtors' mailing address is 675 McDonnell Blvd., Hazelwood, Missouri 63042.

Exhibit No.	Document Description
8.	<i>Order Granting the Debtors' Supplemental Motion for Injunctive Relief Pursuant to 11 U.S.C. § 105</i> , dated Dec. 4, 2020, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD), Adv. Pro. No. 20-50850 (JTD) [Adv. Docket No. 180]
9.	<i>Complaint</i> , dated Apr. 6, 2017, <i>City of Rockford v. Mallinckrodt ARD Inc., et al.</i> , No. 3:17-cv-50107 (IDJ) (LAJ) (N.D. Ill.) [Docket No. 1] (appended to Reply as <u>Exhibit D</u>)
10.	<i>Second Amended Class Action Complaint</i> , dated Dec. 8, 2017, <i>City of Rockford v. Mallinckrodt ARD Inc., et al.</i> , No. 3:17-cv-50107 (IDJ) (LAJ) (N.D. Ill.) [Docket No. 98]
11.	<i>Order & Memorandum Opinion and Order</i> , dated Jan. 25, 2019, <i>City of Rockford v. Mallinckrodt ARD Inc., et al.</i> , No. 3:17-cv-50107 (IDJ) (LAJ) (N.D. Ill.) [Docket Nos. 177 & 178] (appended to Reply as <u>Exhibit E</u>)
12.	<i>City of Rockford v. Mallinckrodt ARD Inc.</i> , 360 F. Supp. 3d 730, 776-77 (N.D. Ill. 2019), <i>reconsideration denied</i> , No. 17 C 50107, 2019 WL 2763181 (N.D. Ill. May 3, 2019) (appended to Reply as <u>Exhibit F</u>)
13.	<i>Mallinckrodt's Motion to Transfer Venue</i> , dated Jan. 27, 2021, <i>City of Rockford v. Mallinckrodt ARD Inc., et al.</i> , No. 3:17-cv-50107 (IDJ) (LAJ) (N.D. Ill.) [Docket No. 533] (appended to Reply as <u>Exhibit G</u>)
14.	<i>Notice to Defend & Civil Action Complaint</i> , dated May 25, 2018, <i>Int'l Union of Operating Eng'rs Local 542 v. Mallinckrodt ARD, Inc., et al.</i> , Case No. 2018-14059 (Pa. Ct. Com. Pl.) [Docket No. 1]
15.	<i>Notice to Defend & Amended Civil Action Complaint</i> , dated Aug. 27, 2018, <i>Int'l Union of Operating Eng'rs Local 542 v. Mallinckrodt ARD, Inc., et al.</i> , Case No. 2018-14059 (Pa. Ct. Com. Pl.) [Docket No. 79]
16.	<i>Mallinckrodt Defendants' Notice of Removal</i> , dated Jan. 8, 2021, <i>Int'l Union of Operating Eng'rs Local 542 v. Mallinckrodt ARD Inc., et al.</i> , No. 2:21-cv-00114-BMS (E.D. Pa.) [Docket No. 1] (appended to Reply as <u>Exhibit I</u>)
17.	<i>Order & Memorandum</i> , dated Mar. 10, 2021, <i>Int'l Union of Operating Eng'rs Local 542 v. Mallinckrodt ARD Inc., et al.</i> , No. 2:21-cv-00114-BMS (E.D. Pa.) [Docket Nos. 16 & 17] (appended to Reply as <u>Exhibit J</u>)
18.	<i>Order</i> , dated June 23, 2021, <i>Int'l Union of Operating Eng'rs Local 542 v. Mallinckrodt ARD Inc., et al.</i> , C.A. No. 21-647 (MN) (D. Del.) [Docket No. 36]
19.	<i>Complaint</i> , dated May 21, 2019, <i>Acument Glob. Techs., Inc. v. Mallinckrodt ARD Inc., et al.</i> , Case No. CT-2275-19 (Tenn. Cir. Ct.)
20.	<i>Order Motions to Dismiss</i> , dated Feb. 21, 2020, <i>Acument Glob. Techs., Inc. v. Mallinckrodt ARD Inc., et al.</i> , Case No. CT-2275-19 (Tenn. Cir. Ct.) (appended to Reply as <u>Exhibit K</u>)

Exhibit No.	Document Description
21.	<i>Mallinckrodt Defendants' Notice of Removal</i> , dated Jan. 8, 2021, <i>Acument Glob. Techs., Inc. v. Mallinckrodt ARD Inc., et al.</i> , Case No. 2:21-cv-02024-JTF-TMP (W.D. Tenn.) (appended to Reply as <u>Exhibit L</u>)
22.	<i>Mallinckrodt's Motion to Transfer Venue</i> , dated Jan. 28, 2021, <i>Acument Glob. Techs., Inc. v. Mallinckrodt ARD Inc., et al.</i> , Case No. 2:21-cv-02024-JTF-TMP (W.D. Tenn.) [Docket No. 7] (appended to Reply as <u>Exhibit M</u>)
23.	<i>Civil Class Action Complaint</i> , Jul. 12, 2019, <i>Steamfitters Local Union No. 420 v. Mallinckrodt ARD LLC, et al.</i> , Case No. 2:19-cv-03047-BMS (E.D. Pa.) [Docket No. 1]
24.	<i>Mallinckrodt's Motion to Transfer Venue</i> , dated Jan. 27, 2021, <i>Steamfitters Local Union No. 420 v. Mallinckrodt ARD LLC, et al.</i> , Case No. 2:19-cv-03047-BMS (E.D. Pa.) [Docket No. 90] (appended to Reply as <u>Exhibit N</u>)
25.	<i>Class Action Complaint</i> , dated Nov. 22, 2019, <i>United Association of Plumbers & Pipefitters Local 322 of S. N.J. v. Mallinckrodt ARD, LLC, et al.</i> , Case No. CAM-L-004696-19, Transaction ID LCV20192163842 (N.J. Supp. Ct. Law Div.) (appended to Reply as <u>Exhibit O</u>)
26.	<i>Amended Complaint</i> , Feb. 20, 2020, <i>United Association of Plumbers & Pipefitters Local 322 of S. N.J. v. Mallinckrodt ARD, LLC, et al.</i> , Case No. 1:20-cv-00188-RBK-KMW (D.N.J.) [Docket No. 40]
27.	<i>Order & Opinion</i> , dated Aug. 18, 2020, <i>United Association of Plumbers & Pipefitters Local 322 of S. N.J. v. Mallinckrodt ARD, LLC, et al.</i> , Case No. 1:20-cv-00188-RBK-KMW (D.N.J.) [Docket Nos. 76 & 77] (appended to Reply as <u>Exhibit P</u>)
28.	<i>Notice of Motion to Transfer Venue Pursuant to 28 U.S.C. § 1412</i> , dated Jan. 27, 2021, <i>United Association of Plumbers & Pipefitters Local 322 of S. N.J. v. Mallinckrodt ARD, LLC, et al.</i> , Case No. 1:20-cv-00188-RBK-KMW (D.N.J.) [Docket No. 90] (appended to Reply as <u>Exhibit Q</u>)
29.	<i>Complaint</i> , dated Aug. 8, 2019, <i>Humana Inc. v. Mallinckrodt ARD LLC, et al.</i> , Case No. 2:19-cv-06926-DSF-MRW (C.D. Cal.) [Docket No. 1] (appended to Reply as <u>Exhibit R</u>)
30.	<i>Second Amended Complaint</i> , dated Apr. 24, 2020, <i>Humana Inc. v. Mallinckrodt ARD LLC, et al.</i> , Case No. 2:19-cv-06926-DSF-MRW (C.D. Cal.) [Docket No. 60]
31.	<i>Humana Inc. v. Mallinckrodt ARD LLC</i> , Case No. 2:19-cv-06926-DSF-MRW, 2020 WL 5640553 (C.D. Cal. Aug. 14, 2020) (appended to Reply as <u>Exhibit S</u>)
32.	<i>Humana Inc. v. Mallinckrodt ARD LLC</i> , Case No. 2:19-cv-06926-DSF-MRW, 2020 WL 3041309 (C.D. Cal. March 9, 2020) (appended to Reply as <u>Exhibit T</u>)

Exhibit No.	Document Description
33.	<i>Order Granting Defendant's Motion to Transfer</i> , dated Jun. 28, 2021, <i>Humana Inc. v. Mallinckrodt ARD LLC, et al.</i> , Case No. 2:19-cv-06926-DSF-MRW (C.D. Cal.) [Docket No. 99] (appended to Reply as <u>Exhibit U</u>)
34.	Proof of Claim No. 3396, filed by Humana, Inc. against Debtor Mallinckrodt ARD LLC ²
35.	Proof of Claim No. 4132, filed by United HealthCare Services, Inc., on behalf of itself, its affiliates, its subsidiaries, and its parents that either administer health plans, sponsor health plans, or offer fully insured health insurance plans, against Debtor IMC Exploration Company ³
36.	Proof of Claim No. 5737, filed by OptumRx Group Holdings, Inc. and OptumRx Holdings, LLC, on behalf of themselves and their pharmacy subsidiaries, against Debtor Mallinckrodt Critical Care Finance LLC ⁴
37.	Proof of Claim No. 4373, filed by City of Rockford, Illinois against Debtor Infacare Pharmaceutical Corporation ⁵ [SUPPRESSED]
38.	Proof of Claim No. 6047, filed by Acument Global Technologies, Inc. against Debtor IMC Exploration Company ⁶ [SUPPRESSED]
39.	<i>Acthar Plaintiffs' Motion to Compel Discovery</i> , dated May 20, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 2487]
40.	<i>Order Authorizing Intercompany Restructuring Transactions</i> , dated Nov. 25, 2020, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 633]
41.	Form 8-k of Assertio Therapeutics, Inc., dated Feb. 7, 2020 (https://sec.report/Document/0001104659-20-012450/)
42.	Document Bates-numbered MNK05586900 (Slide deck titled "Meeting of the Board of Directors of Mallinckrodt plc" and dated July 16, 2015) (appended to Reply as <u>Exhibit V</u>) [SEALED]
43.	Document Bates-numbered MNK0431963 (Slide deck regarding "ARD Contracting Entities" (undated)) (appended to Reply as <u>Exhibit W</u>) [SEALED]

² Humana, Inc. filed proofs of claim, each substantially similar to Exhibit No. 34, against each of the Debtors.

³ United HealthCare Services, Inc. filed proofs of claim, each substantially similar to Exhibit No. 35, against each of the Debtors.

⁴ OptumRx Group Holdings, Inc. and OptumRx Holdings, LLC filed proofs of claim, each substantially similar to Exhibit No. 36, against each of the Debtors.

⁵ City of Rockford, Illinois filed proofs of claim, each substantially similar to Exhibit No. 37, against each of the Debtors.

⁶ Acument Global Technologies, Inc. filed proofs of claim, each substantially similar to Exhibit No. 38, against each of the Debtors.

Exhibit No.	Document Description
44.	Document Bates-numbered MNK05503705 (Email chain with subject “MNK – Acthar IP Sale – Executed documents” dated Dec. 11-12, 2014) (appended to Reply as <u>Exhibit X</u>) [SEALED]
45.	Document Bates-numbered MNK01443823 (Email chain with subject “MPIL Board Meeting – S&T Update” dated Mar. 4, 2016) [SEALED]
46.	Document Bates-numbered MNK01577675 (Email chain with subject “Risks Associated with Acthar Price Increase” dated Dec. 4-5, 2015) [SEALED]
47.	Document Bates-numbered MNK01444020 (Email chain with subject “ARD Strat Plan and QBR” dated Mar. 8-9, 2016) (appended to Reply as <u>Exhibit Y</u>) [SEALED]
48.	Document Bates-numbered MNK03183310 (Materials from Nov. 3, 2016 Special Board Meeting of Mallinckrodt Pharmaceuticals Limited (UK)) [SEALED]
49.	<i>Stipulation and Agreement Permitting Third Party Payors to File Consolidated Proofs of Claim under a Single Case Number</i> , dated Jan. 26, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 1292-1]
50.	Transcript of Videotaped Deposition of Stephen Welch, conducted June 11, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) (appended to Reply as <u>Exhibit Y</u>) (“ <i>Welch Dep. Tr.</i> ”) [SEALED]
51.	<i>Attestor Limited and Humana Inc.’s Notice of Deposition of Debtors Pursuant to Fed. R. Civ. P. 30(b)(6) and Fed. R. Bankr. P. 7030</i> , dated May 12, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 2284] (<u>Exhibit 1</u> to Welch Dep. Tr.)
52.	Document Bates-numbered MNK_ACTH_00000046 (Chart depicting corporate structure dated as of September 25, 2020) (<u>Exhibit 2</u> to Welch Dep. Tr.) [SEALED]
53.	<i>Debtors’ First Omnibus Objection to Unsubstantiated Claims (Substantive)</i> , dated Apr. 30, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 2165] (<u>Exhibit 3</u> to Welch Dep. Tr.)
54.	Document Bates-numbered MNK_ACTH_00000018-0020 (Legal entity summary dated as of Oct. 11, 2020) (<u>Exhibit 5</u> to Welch Dep. Tr.) [SEALED]
55.	Document Bates-numbered MNK_ACTH_00001700-1704 (Slide deck titled “Mallinckrodt Project Apollo” and dated Jan. 26, 2019) (<u>Exhibit 6</u> to Welch Dep. Tr.) [SEALED]
56.	Document Bates-numbered MNK_ACTH_00001589-1617 (Slide deck titled “Mallinckrodt Project Gemini – Phase I” and dated Oct. 22, 2018) (<u>Exhibit 7</u> to Welch Dep. Tr.) [SEALED]

Exhibit No.	Document Description
57.	Document Bates-numbered MNK_ACTH_00001618-1633 (Slide deck titled “Mallinckrodt Project Gemini – Phase II” and dated Dec. 28, 2018) (<u>Exhibit 8</u> to Welch Dep. Tr.) [SEALED]
58.	Document Bates-numbered MNK_ACTH_00001634-1645 (Slide deck titled “Mallinckrodt Project Gemini – Phase III” and dated Jan. 25, 2019) (<u>Exhibit 9</u> to Welch Dep. Tr.) [SEALED]
59.	Document Bates-numbered MNK_ACTH_00001646-1651 (Slide deck titled “Mallinckrodt Project Gemini – Phase IV” and dated Mar. 20, 2019) (<u>Exhibit 10</u> to Welch Dep. Tr.) [SEALED]
60.	Document Bates-numbered MNK_ACTH_00001432-1487 (“Collaboration Agreement Between Mallinckrodt Pharmaceuticals Limited and Mallinckrodt Pharmaceuticals Ireland Limited”) (<u>Exhibit 11</u> to Welch Dep. Tr.) [SEALED]
61.	Document Bates-numbered MNK_ACTH_00001488-1491 (“First Amendment to Collaboration Agreement” dated as of Feb. 28, 2018) (<u>Exhibit 12</u> to Welch Dep. Tr.) [SEALED]
62.	Document Bates-numbered MNK_ACTH_00001558-1588 (Slide deck titled “Project Easter” and dated Sept. 29, 2017) (<u>Exhibit 13</u> to Welch Dep. Tr.) [SEALED]
63.	Document Bates-numbered MNK_ACTH_00001682-1699 (Slide deck titled “Sonorant Separation Step Plan” and dated Jul. 10, 2020) (<u>Exhibit 14</u> to Welch Dep. Tr.) [SEALED]
64.	Document Bates-numbered MNK_ACTH_00001039 (Excel spreadsheet titled “Mallinckrodt plc and Debtor & Non-Debtor Subsidiaries – Intercompany Trade – Unaudited principal balances”) (<u>Exhibit 15</u> to Welch Dep. Tr.) [SEALED]
65.	<i>Motion of the Debtors for Interim and Final Orders (A) Authorizing Continued Use of Existing Cash Management System, Including Maintenance of Existing Bank Accounts, Checks, and Business Forms, (B) Authorizing Continuation of Existing Deposit Practices, (C) Waiving Certain U.S. Trustee Guidelines, (D) Authorizing Continuation of Intercompany Transactions, and (E) Granting Superpriority Status to Postpetition Intercompany Claims</i> , dated Oct. 12, 2020, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 23] (<u>Exhibit 16</u> to Welch Dep. Tr.)
66.	Document Bates-numbered MNK_OCC&UCC_01556960-6969 (Email chain with subject “MPIL IP slides” dated Feb. 22, 2017 together with slide deck titled “Mallinckrodt Pharmaceuticals: Acthar Enterprise Steerco Update”) (<u>Exhibit 17</u> to Welch Dep. Tr.) [SEALED]
67.	<i>Motion of Attestor Limited and Humana Inc. for Entry of an Order Allowing and Compelling Payment of Administrative Claims Pursuant to Section 503(b) of the Bankruptcy Code</i> , dated Apr. 30, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 2159]

Exhibit No.	Document Description
68.	<i>Joint Plan of Reorganization of Mallinckrodt plc and Its Debtor Affiliates under Chapter 11 of the Bankruptcy Code</i> , dated Jun. 8, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 2767]
69.	Settlement Agreement appended as Exhibit 1 to <i>Joint Notice of Partial Settlement and Stipulation of Dismissal</i> , filed Sept. 20, 2019, <i>United States ex rel. Strunck. v. Mallinckrodt ARD LLC</i> , Case No. 2:12-cv-00175-BMS (E.D. Pa.) [Docket No. 74-1] (appended to Reply as <u>Exhibit AA</u>)
70.	Department of Health and Human Services Office of Inspector General (“ OIG ”), Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005)
71.	<i>Motion of the Debtors for an Order Granting Leave from Local Rule 3007-1(f) to Permit the Filing of Substantive Omnibus Objections and Granting Related Relief</i> , dated May 1, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 2167]
72.	<i>Motion of Attestor Limited and Humana Inc. for Entry of an Order Pursuant to 11 U.S.C. §§ 105(a) and 502(c) (I) Authorizing Estimation of Humana’s Acthar-Related Claims and (II) Allowing Humana’s Acthar-Related Claims for All Purposes in These Bankruptcy Cases</i> , dated Apr. 30, 2021, <i>In re Mallinckrodt plc, et al.</i> , Case No. 20-12522 (JTD) [Docket No. 2157]
73.	Email chain titled “6/22 Discovery Conference” and dated Jun. 20-21, 2021 (final email sent by B. McCallen on Jun. 21, 2021 at 10:58 a.m.)
74.	Document Bates-numbered MNK_OCC&UCC_00542484 (5/18/2016 Mallinckrodt Pharmaceuticals Executive Committee Meeting - DEMPE Governance Update Presentation)
75.	Document Bates-numbered MNK_OCC&UCC_00262641 (10/5/2017 ARD Leadership Team Meeting)
76.	2/25/2020 Mallinckrodt Form 8-K
77.	12/25/2020 Mallinckrodt plc Form 10-K
78.	2/25/2020 Mallinckrodt Entities Support Agreement
79.	3/16/2020 Mallinckrodt Form 8-K
80.	4/7/2020 Mallinckrodt Form 8-K
81.	Document Bates-numbered MNK_ACTH_00000980 (8/6/2020 Master Cash Management Agreement)
82.	Document Bates-numbered MNK_ACTH_00001705 (12/1/2020 Mallinckrodt Branded IP Restructuring Presentation)
83.	3/10/2021 Mallinckrodt plc Form 10-K
84.	4/2/2021 Mallinckrodt Organization Charts, Exhibit D to Motion for Substantive Consolidation
85.	Proof of Claim No. 3133 - Humana, Inc.
86.	Document Bates-numbered MNK_ACTH_00000190 (Mallinckrodt Pharmaceuticals (MPIL) Organizational Chart)

Exhibit No.	Document Description
87.	Document Bates-numbered MNK04531963 (ARD Contracting Entities Slides)
88.	05/01/2021 Declaration of Randall S. Eisenberg in Support of Debtors Motion for Scheduling Order and Objections to Claims [Dkt. 2166] (Ex. 4 to Welch Depo. Tr. [6/11])

Debtors' Witness
Stephen A. Welch, Chief Transformation Officer
Acthar Insurance Claimants' Witness
Stephen A. Welch, Chief Transformation Officer

The Debtors and Attestor/Humana each reserve the right to designate additional exhibits and/or witnesses for their case-in-chief. Both parties further reserve the right to introduce additional cross-examination and/or rebuttal exhibits at the July 23, 2021 hearing based upon evidence introduced by any other parties at the hearing.